WHITE PAPER

JULY 2022

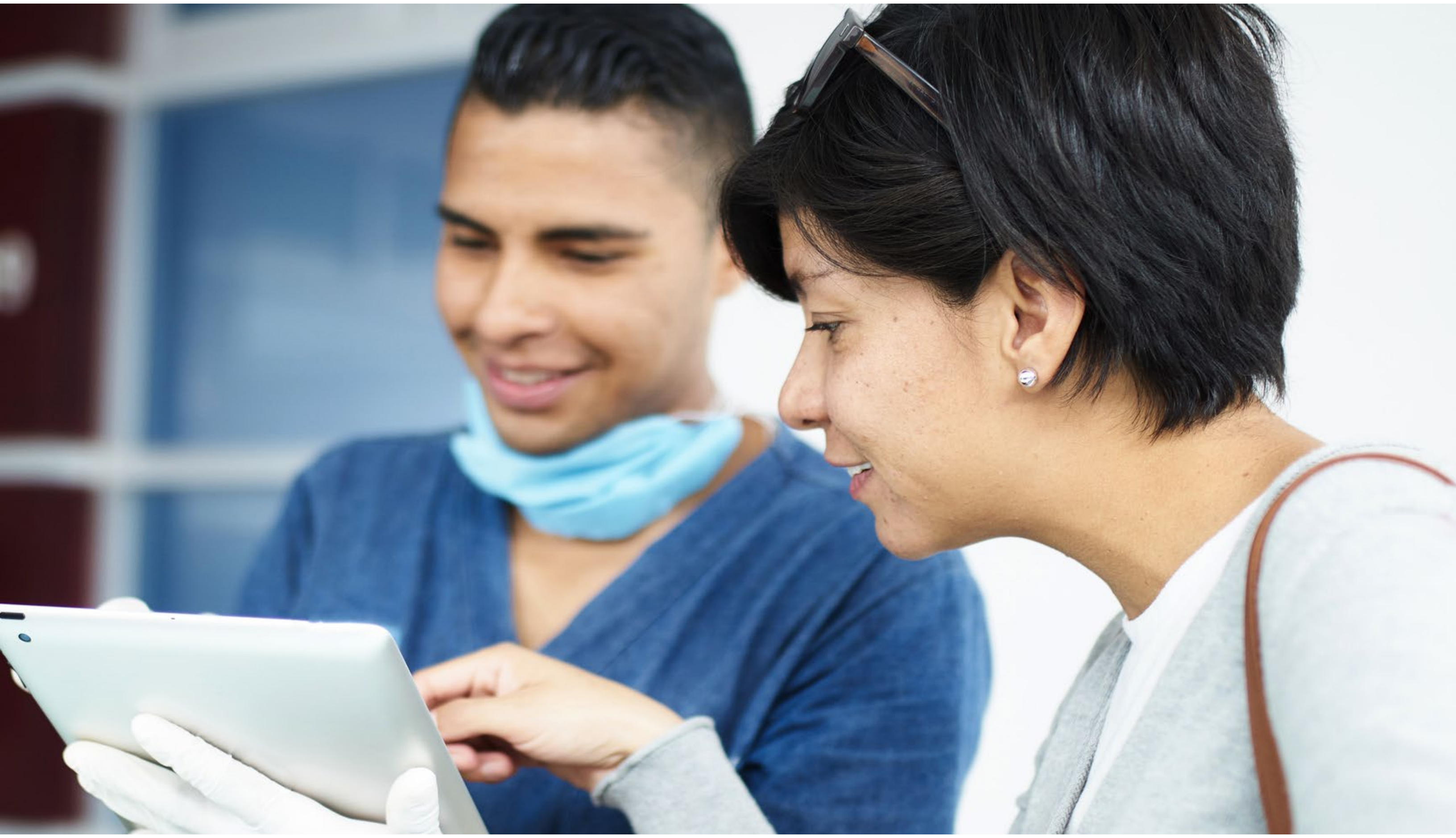
Enhancing Data Infrastructure for Collection and Integration of Patient-Reported Outcomes and other Patient-Generated Health Data across PCORnet® Clinical Research Networks

Presented by:

NORC at the University
of Chicago

Presented to:

Patient-Centered Outcomes
Research Institute (PCORI)



NORC at the University of Chicago

Authors

Prashila Dullabh, MD
Priyanka Desai, PhD, MSPH, CPH
Rachel Kane
Desirae Leaphart, MPH
Lauren Hovey, MA

NORC at the University of Chicago
4350 East-West Highway, 8th Floor
Bethesda, MD 20814

Acknowledgments

NORC at the University of Chicago would like to express its gratitude to the Clinical Research Networks participating in PCORnet®, the Coordinating Center for PCORnet, and the subject matter experts that generously offered their expertise and time. Additionally, we would like to thank the attendees of the "Expanding Patient-Reported Outcomes and Patient-Generated Health Data across PCORnet®" webinar. Their contributions helped us develop an on-the-ground understanding of the current progress, successes, challenges, and opportunities for increasing patient-reported outcomes and patient generated health data availability and accessibility across PCORnet. We would also like to acknowledge the guidance provided by Claudia Grossmann, Nik Koscielniak, Julianna Paris, Penny Mohr, and Erin Holve on this project.

Suggested Citation

Dullabh, P., Desai, P., Kane, R., Leaphart, D., & Hovey, L. Enhancing Data Infrastructure for Collection and Integration of Patient-Reported Outcomes and other Patient-Generated Health Data across PCORnet® Clinical Research Networks. Patient Centered Outcomes Research Institute; July 2022. Prepared by NORC at the University of Chicago under Contract No. IDIQ-TO#27-NORC-SCI-AOSEPP-05-24-2021

Disclaimer

All statements, findings, and conclusions in this publication are solely those of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI) or its Board of Governors. This publication was developed through a contract to support PCORI's work. Questions or comments may be sent to PCORI at info@pcori.org or by mail to Suite 900, 1828 L Street, NW, Washington, DC 20036.

Table of Contents

Executive Summary

The Patient-Centered Outcomes Research Institute (PCORI®) is undertaking a series of data convenings as it considers data infrastructure enhancements to PCORnet®, the National Patient-Centered Clinical Research Network. PCORnet® is a large, nationally representative "network of networks" funded by PCORI® to improve the nation's capacity to efficiently conduct definitive patient-centered health research, particularly comparative clinical effectiveness research (CER). PCORnet follows a distributed research network model and is national in scope, and participants include Clinical Research Networks (CRNs) comprising multiple health systems, health system patient partners, and a Coordinating Center. The PCORnet distributed structure permits direct connections to patients and providers in the access and re-access of primary data, with appropriate governance, privacy, and confidentiality protections consistent with legal requirements. These partnerships allow researchers to query millions of clinical, claims, and registry records to support efficient, high-impact CER within a secure, privacy-preserving structure.

PCORnet offers a unique context in which to understand the national landscape of CER-related data, and an opportunity to identify potential data enhancement to deepen understanding of patient experiences and outcomes. Such an opportunity is only possible because of the distributed research network model and national scope of PCORnet. PCORI plans to prioritize investments in PCORnet infrastructure enhancements that build on the unique capabilities of the PCORnet data structures and align with PCORI's five National Priorities for Health.[1] The National Priorities for Health, which will guide PCORI's work in the years ahead, were adopted by PCORI's Board of Governors in October 2021 and include:

1. Increase Evidence for Existing Interventions and Emerging Innovations in Health
2. Enhance Infrastructure to Accelerate PCOR
3. Advance the Science of Dissemination, Implementation, and Health Communication,
4. Achieve Health Equity
5. Accelerate Progress Toward an Integrated Learning Health System.

---

[1] In 2021, the PCORI Board of Governors also approved a set of Prioritizing Principles for Infrastructure Funding Relating to PCORnet to guide decision-making about PCORI infrastructure funding for the next stages of PCORnet. These Priorities include: "IV. Build on the unique capabilities of the PCORnet data structures, prioritizing investments that will align with the PCORI Strategic Research Priorities." And " Recognize, enable, and promote the value of PCORnet to contribute to a learning health care system through effective partnerships with all stakeholders."

In alignment with these National Priorities for Health, PCORI identified three areas of interest for data infrastructure enhancements:1) social determinants of health (SDOH); 2) patient-reported outcomes (PROs) and other patient-generated health data (PGHD); and 3) Centers for Medicare & Medicaid Services (CMS) claims data. All three opportunities for data infrastructure enhancement have potential to increase data capture, availability, and use across PCORnet® CRNs.[2] This White Paper identifies several strategic opportunities for PROs and PGHD, including enhancements to the PCORnet® Common Data Model (CDM), a standardized model for harmonizing and representing Network data in a consistent format. The enhancements could greatly contribute to the Network's ability to conduct definitive national studies that advance evidence-based approaches to improve health outcomes and health equity.

Under contract from PCORI, NORC at the University of Chicago (NORC) is assessing opportunities in these three areas. This White Paper focuses on the second of the three areas—opportunities related to PROs and PGHD. These opportunities within PCORnet build on the important investments PCORI has made in its portfolio of methodological research regarding the integration, interpretation, and use of PROs and other patient-centered outcomes in the conduct of CER[3]. In addition, PCORI's 2017 *Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records*[4] provided an early framework for decisions health systems may make to implement PROs in the electronic health record (EHR).

For the purposes of this paper, PRO and PGHD are defined as follows:

- **PRO**: A measurement based on a report directly from the patient (or their designated proxy) about the status of a patient's health condition without amendment or interpretation of the patient's response.
- **PGHD**: Health-related data created, recorded, or gathered outside a clinical setting—through a mobile application, device, or patient portal—by or from patients (or family members and other caregivers).

This paper articulates NORC's findings on the current state of PROs and PGHD collection across PCORnet® CRNs, along with challenges and opportunities for

---

[2] Clinical Research Networks (CRNs) consist of two or more health systems (e.g., hospitals, integrated delivery systems, federally qualified health centers) who have formed a network. The CRN facilitates data capture, standardization, and data sharing within its own network and has also chosen to join the "network of networks" known as PCORnet.

[3] https://www.pcori.org/assets/The-Design-and-Selection-of-Patient-Reported-Outcomes-Measures-for-Use-in-Patient-Centered-Outcomes-Research.pdf

[4] Snyder C, and Wu, A.W., eds. Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Baltimore, MD: Johns Hopkins University. 2017. Funded by Patient-Centered Outcomes Research Institute (PCORI); JHU Contract No. 10.01.14 TO2 08.01.15. Available at: http://www.pcori.org/document/users-guide-integrating-patient-reported-outcomes-electronic-health-records

expanding PCORnet infrastructure to increase the availability and accessibility of PROs and PGHD within CRNs. Congressional reauthorization of PCORI in 2019 mandates that PCORI-funded studies should capture the full range of clinical and patient-centered outcomes when appropriate and relevant, including the potential burdens and impacts of various healthcare services along with the relative patient-centered health outcomes and clinical effectiveness measures that PCORI-funded research has captured to date. Improving capabilities and value in capturing and loading these data in the PCORnet infrastructure are a critical next step to ensure an ecosystem of PROs and PGHD support ongoing innovation of PCOR studies. PROs and PGHD are necessary to conduct more patient-engaged research that is inclusive of diverse patient perspectives, which in turn makes research more equitable and inclusive[5]. These data can be reported and used in the context of a patient's other health data (e.g., laboratory reports, imaging studies, clinic notes) to promote patient-centered clinical care and research.

Methods. The findings in this White Paper are based on a survey of health systems participating in PCORnet; a literature review; key informant interviews (KIIs) with stakeholders associated with PCORI, PCORnet® CRNs, and those with expertise in data infrastructure for the collection and standardization of PROs and PGHD. In December 2021, NORC hosted a public webinar which presented initial findings and opportunities for PROs and PGHD from the survey and interviews with key informants.

Current State. The survey provided insights into the current landscape of PROs and PGHD collection and use among 53 of the 75 health systems participating in PCORnet.

Patient Reported Outcomes

- Most health systems that completed the survey reported that they are collecting PROs as part of clinical care. Approximately 78 percent of health systems collecting PROs are using Patient-Reported Outcomes Measurement Information System (PROMIS®) measures, followed by 34 percent of health systems reporting collecting HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems).
- The extent to which there are common PRO measures used across health systems is unclear. As many as 500 distinct PROs may be collected across PCORnet® CRNs, though health systems indicate there are few consistently collected measures. Top responses included behavioral health measures such as the PHQ-9 (Patient Health Questionnaire-9) (n=15), PHQ-2 (Patient Health Questionnaire-2)

---

[5] Calvert, M.J., Cruz Rivera, S., Retzer, A. *et al.* Patient reported outcome assessment must be inclusive and equitable. *Nat Med* (2022). https://doi.org/10.1038/s41591-022-01781-8

(n=8), GAD-7 (General Anxiety Disorder-7) (n=7), and AUDIT (Alcohol Use Disorders Identification Test) (n=5).

- Integration of PRO data into EHR varies greatly across health systems. Nearly half of health systems that currently collect PRO data reported they have full EHR integration (i.e., PRO data are computable in the EHR).
- Over half of health systems that completed the survey stated that they were planning to expand PRO collection. These plans included expanding PRO collection to all clinical specialties and improving processes for collecting PRO data to reduce patient burden on tasks like filling out forms.

Patient Generated Health Data

- For many health systems, PGHD collection is still at an early stage, with limited EHR integration. Health systems that are collecting PGHD are primarily focused on collecting biometric data, symptoms, and health history. These data are most commonly collected through the patient portal.
- Multiple health systems report having plans to expand PGHD collection within the next 2 to 4 years.

Opportunities. Based on the current state of PCORnet data infrastructure and the existing PRO data and PGHD across PCORnet® CRNs, challenges and opportunities for expansion and investment were identified in four areas:

- **Engaging Stakeholders around PRO Data Priorities for the PCORnet® CDM, Clinical Care, and Research**
  - *Engage PCORnet® CRNs and other stakeholders around the value of collecting PRO data as part of clinical care for downstream use in research:* While many systems and CRNs are collecting PRO data, both key informants and webinar participants noted that the widespread collection of PRO data remains limited. The 2021 survey found that some systems were not actively collecting PROs at the time of the survey. Key informants recommended broader discussions with health systems regarding the value of collecting PRO measures during clinical care and then capturing these PRO data within the PCORnet® CDM for research. In particular, there is a need to improve understanding among stakeholders of the shared value proposition between PCORnet, patients, clinicians, and health systems in the collection and use of PRO data for clinical care. These conversations may also be an opportunity to identify PRO measures that are both primed for standardization and meaningful to patients, clinicians, and other stakeholders to accelerate progress towards an integrated learning health system. (Short-term)

  - *Engage PCORnet® CRNs and other stakeholders to stabilize Network mapping and loading procedures for the PCORnet® CDM PRO Common Measures (PRO-CM) table:* Researchers have different interpretations of where PRO data should be mapped to fields in the PCORnet® CDM. Reconciling mapping for each individual study can be time consuming and create delays in research completion. While resources to populate and refresh the PRO-CM table are important, as described above, an additional opportunity would involve convening PCORnet® Network Partners to stabilize Network procedures for how they are mapping data to the PRO-CM table and identifying inconsistencies across systems. This may have the potential to create efficiencies for study investigators and support PRO data capture. (Short-term)

- **Leveraging PRO Data Collected as Part of Routine Clinical Care**
  - *Conduct additional analysis to identify commonly used PRO measures across PCORnet that can be standardized and leveraged for the PCORnet® CDM*: While this White Paper identifies a set of PROs that are most common across the health systems participating in PCORnet, additional information is needed. For example, while many PRO measures are validated and standardized, health systems may use different versions of the same instruments. Even with common, standardized instruments, capturing PRO data from EHRs and transforming these data into the PCORnet® CDM specifications requires local development of extract, transform, and load (ETL) processes. Additional quality improvement and ETL testing efforts could identify the full range of PROs collected by health systems within CRNs to determine a subset of common measures that could then be standardized across PCORnet® CRNs. Supporting the development of processes, workflows, and guidelines for standardizing PRO measures for specific use cases (e.g., oncology, orthopedics, behavioral health) would build capacity for PRO data capture in the PCORnet® CDM. (Mid-term)
  - *Enhance resources for data curation processes to ensure that the existing PRO-CM table in the PCORnet® CDM are "research ready":* Current PCORnet quarterly data curation processes do not require sites to load data into the PRO-CM table of the PCORnet® CDM. Therefore, quality checks for "research readiness" do not occur until a relevant, study-specific query (i.e., research question) is submitted to CRNs by the Coordinating Center for PCORnet. The "research readiness" of available PRO data may be limited as there are differences in the latency of PRO data, the use of item-level scores or summary scores, and where PRO data elements are coded in the PCORnet® CDM. Additional steps can be taken to ensure the data are research ready, such as providing resources to populate and refresh the PRO-CM data table. (Mid-term)

- **Facilitating the Loading and Use of PRO Data Collected During Research**
  - *Develop a repository of PRO questionnaires for sites to use:* CRNs serve as venues for prospective collection of PRO data as part of research. For research studies, PRO data are often collected via platforms such as REDCap, with research teams developing study-specific data dictionaries and PRO instruments. This introduces heterogeneity in how and which PROs are collected. Supporting the development of a repository of PRO instruments— initially focusing on a small set of measures that are used frequently across research studies (e.g., PHQ-9, PROMIS measure sets) — that are importable within survey platforms would help reduce the heterogeneity of PRO data collected for research. (Mid-term)
  - *Identify data infrastructure supports locally (i.e., for health systems participating in PCORnet) for PRO data collection:* PRO data collected as part of research are not routinely loaded into the PCORnet® CDM because researchers are used to their existing workflows and developing site-specific ETL processes is resource intensive. Supporting and bolstering local infrastructure at health systems or across CRNs participating in PCORnet may resolve issues at sites in terms of capturing and loading PRO data into the PCORnet® CDM. (Short-term)
  - *Explore centralized data infrastructure and services (i.e., across the PCORnet® CRNs) for PRO data collection:* As an alternative or in addition to bolstering local data infrastructure, there may be an opportunity to centralize some functions for PRO data collection at the level of the Coordinating Center for PCORnet. A centralized approach, such as establishing or leveraging an existing centralized platform for data collection in PCORnet designated studies, would standardize PRO collection and support the seamless translation of data into the PCORnet® CDM. (Long-term)
- **Enhancing the PCORnet Data Infrastructure to Load and Leverage PGHD for Research**
  - *Explore what platforms and technologies PCORnet Network Partners use to collect PGHD (e.g., apps, portals, EHRs, third-party):* The collection, use, and standardization of other PGHD—specifically, data from wearables, medical devices, and patient portals—is still in an emergent stage across PCORnet® CRNs; however, the types of platforms used and their performance across the Network is relatively unknown. Existing data collection platforms can facilitate use of PGHD for research across the CRN sites by supporting the collection of PGHD and allowing for this data to be linked to data from PCORnet® CRNs. A more in-depth exploration of the types of platforms and technology that Network

sites use to capture PGHD and understanding what PGHD sites access would inform the development of upgrades to the PCORnet® CDM for loading PGHD from various sources. (Short-term)

- *Pilot modifications to the PCORnet® CDM specification that support the loading of a standardized set of PGHD:* The survey found that several health systems participating in PCORnet see increased capacity for the capture and integration of PGHD as a broader goal for their system. Currently, the PCORnet® CDM does not support the capture of PGHD collected from patient portals, wearable devices, and medical devices. Gaining buy-in from CRNs and piloting modifications to the PCORnet® CDM would support the capture of PGHD—starting with the inclusion of dedicated fields for promising use cases (e.g., home blood pressure machines, glucometers) and, in the longer-term, developing and piloting a separate PGHD table. Additionally, these PGHD modifications to the PCORnet® CDM should align with the emerging Fast Healthcare Interoperability Resources (FHIR®) standards in this field; however, this is also a longer-term opportunity. (Mid- and long-term)

Conclusions. Expanding PCORnet data resources to include more robust PROs and PGHD concepts is critical to achieve PCORI's Phase 3 goal of using PCORnet to conduct definitive national studies that advance PCORI's National Priorities for Health, including efforts to accelerate progress towards a learning health system. The opportunities discussed in this White Paper represent potential enhancements to PCORnet® data infrastructure that may increase PRO data and other PGHD availability and accessibility across PCORnet® CRNs. While significant progress has been made to capture PROs through the EHR and integrate PROs into the EHR from other sources, there are considerable unknowns related to the availability of data for PCOR. Specifically, it is unclear to what extent well-validated measures are consistently collected and computable, enabling PCOR studies that utilize real-world clinical data to access meaningful patient-centered measures of outcomes.

This assessment of the PRO and PGHD landscape—based on the literature and discussions with experts and interested stakeholders—identifies opportunities within four thematic areas to be undertaken in the short-, mid-, and long-term. Improving PCORnet capabilities and value by capturing and loading PROs and PGHD in the PCORnet® CDM will enhance the availability and accessibility of these data to support the next generation and innovation of PCOR studies. PROs and PGHD are essential to inform PCOR and greater access to standardized PROs and PGHD within PCORnet has great potential to enhance insights into a patient's or population's health status, function, symptom burden, adherence, health behaviors, and quality of life.

1. Introduction

The Patient-Centered Outcomes Research Institute (PCORI®) is undertaking a series of data convenings for PCORnet®, the National Patient Centered Clinical Research Network. The convenings comprise a multi-step assessment process to identify potential enhancements to the PCORnet® data infrastructure, including the PCORnet® Common Data Model (CDM). As part of this process, PCORI® contracted with NORC at the University of Chicago (NORC) to explore opportunities to advance the PCORnet data infrastructure in the three areas: 1) social determinants of health (SDOH); 2) patient-reported outcomes (PROs) and other patient generated health data (PGHD); and 3) access to Centers for Medicare & Medicaid Services (CMS) claims data. This White Paper focuses on the second of the three—opportunities related to PROs and PGHD.

For the purposes of this paper, PRO and PGHD are defined as follows:

- **PRO:** A measurement based on a report directly from the patient (or their designated proxy) about the status of a patient's health condition without amendment or interpretation of the patient's response.[1]
- **PGHD:** Health-related data created, recorded, or gathered outside a clinical setting— through a mobile application, device, or patient portal—by or from patients (or family members and other caregivers).[2]

1.1 Background

PCORnet® is a large, nationally representative "network of networks" funded by PCORI® to improve the nation's capacity to efficiently conduct definitive health research, particularly comparative effectiveness research (CER). In 2021, PCORI's Board of Governors undertook several efforts to set strategic priorities, including adopting PCORI's five National Priorities for Health[6] in October 2021. These National Priorities for Health, which will guide PCORI's work in the years ahead, are:

1. Increase Evidence for Existing Interventions and Emerging Innovations in Health
2. Enhance Infrastructure to Accelerate Patient-Centered Outcomes Research (PCOR)
3. Advance the Science of Dissemination, Implementation, Health Communication,
4. Achieve Health Equity
5. Accelerate Progress Toward an Integrated Learning Health System.

---

[6] PCORI's National Priorities for Health

PCORI plans to prioritize investments in PCORnet infrastructure enhancements that build on the unique capabilities of the PCORnet data structures and align with PCORI's National Priorities for Health.[7]

The work described in this White Paper aims to inform and advance these National Priorities for Health, with a focus on two in particular: *Enhance Infrastructure to Accelerate PCOR* and *Increase Evidence for Existing Interventions and Emerging Innovations in Health*. Enhancing PCORnet data infrastructure by increasing collection of PRO data and PGHD concepts in PCORnet data resources (e.g., PCORnet® CDM) is critical to improve availability and use of these data across PCORnet® Clinical Research Networks (CRNs). These PROs and PGHD are integral to increasing the evidence for existing interventions and innovations by building better data capacity on the "whole person". Improving the availability and accessibility of these data in the PCORnet infrastructure will ensure an ecosystem of PROs and PGHD to support the next generation and innovation of PCOR studies. Additionally, this will support PCORI's Phase 3 goal of using PCORnet to conduct definitive national studies that advance PCORI's National Priorities for Health, including accelerating progress toward a learning health system.

The PROs opportunities within PCORnet also build on the important investments PCORI has made in its portfolio of methodological research regarding the integration, interpretation, and use of PROs and other patient-centered outcomes in the conduct of CER.[3] In addition, PCORI's 2017 *Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records* [4] provided an early framework for decisions health systems may make to implement PROs in the electronic health record (EHR).

NORC has been tasked with reviewing the PRO and PGHD resources available through the CRNs participating in PCORnet and suggesting mechanisms for their enhancement. PCORnet is a national resource funded by PCORI that supports efficient, effective, and impactful CER.[5] PCORnet consists of multiple CRNs, patient partners, and a Coordinating Center that all work together to improve data access, patient engagement, and partnerships for patient-centered outcomes research.

Each CRN encompasses multiple health systems, such as hospitals, integrated delivery systems, and federally qualified health centers (FQHCs) (see Figure 1 and Appendix B).

---

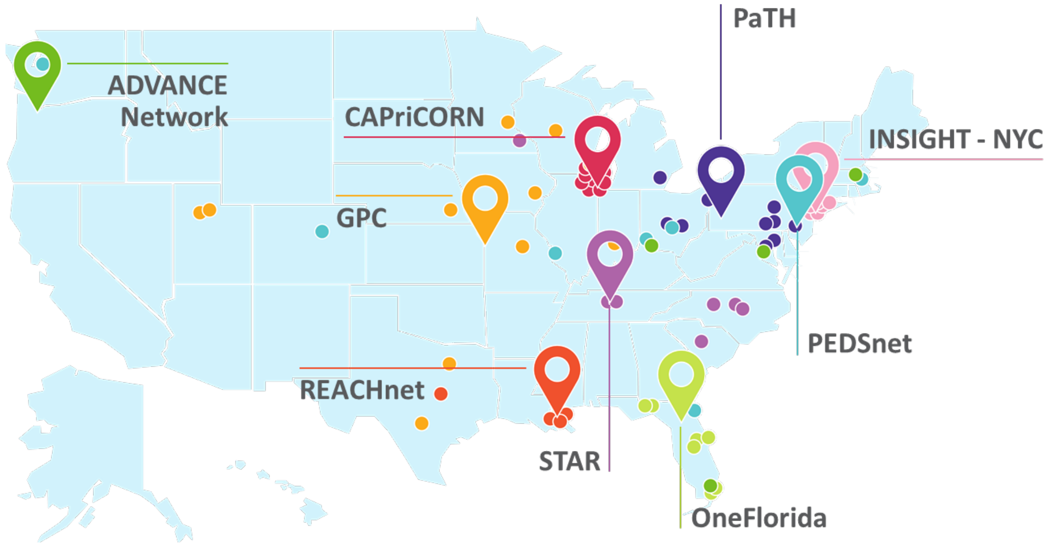
[7] In 2021, the PCORI Board of Governors also approved a set of Prioritizing Principles for Infrastructure Funding Relating to PCORnet to guide decision-making about PCORI infrastructure funding for the next stages of PCORnet. These Priorities include: "IV. Build on the unique capabilities of the PCORnet data structures, prioritizing investments that will align with the PCORI Strategic Research Priorities." And "Recognize, enable, and promote the value of PCORnet to contribute to a learning health care system through effective partnerships with all stakeholders."

The Coordinating Center for PCORnet supports the maintenance of data and research infrastructure to facilitate research. PCORnet also includes patient partners, who participate in all Network governance, provide input from a patient perspective on research design and implementation and on approaches to patient engagement and patient-centeredness.

As a patient-centered initiative, patient engagement and the protection of individual privacy are core values for PCORnet. The PCORnet infrastructure is compliant with applicable laws, regulations, and legal requirements, including but not limited to those governing privacy, security, data, research, and human subjects and a statement on the PCORnet privacy-protection infrastructure is publicly available here. PCORnet is a distributed research network model that includes standardized data and multiple health systems and data marts. In this model data holders (e.g., health systems) maintain physical control, use, and manage transfer of their data. A key security feature of the PCORnet infrastructure is that the data stay with each network partner behind its firewall protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and are not amassed into a single data pool or data warehouse.

Given the national scale and distributed network features of PCORnet, the Network offers a unique context in which to understand the national landscape of CER data. In particular, the number of diverse health systems participating in PCORnet offers an important perspective on the current capacity of PCORnet partners to assess patient experiences and outcomes.

Figure 1. Clinical Research Networks (CRNs) participating in PCORnet, December 2021*



**CAPriCORN is no longer participating in PCORnet.*

Source: Developed by the Duke Clinical Research Institute (DCRI) with funding through a PCORI Award (CC2-Duke-2016-TO12). Used with permission from PCORI.

The PCORnet® CDM is one of the resources PCORnet participants use to enhance the usability and "research readiness" of data available via the CRNs. The PCORnet® CDM standardizes data from the CRNs into a consistent format. Data are collected by health systems participating in PCORnet through a variety of processes and are transformed into the PCORnet® CDM, which is conducted at either the health system level or by the CRN. Once in the PCORnet® CDM, deidentified data are sent to the Coordinating Center for PCORnet and undergo a data curation process and quarterly quality control checks, and if approved, are considered research ready.

PCORnet® CRNs began efforts related to PRO collection in 2014, when the PCORnet PRO Task Force, in collaboration with the NIH Collaboratory, developed consensus-based definitions for both PROs and PGHD in order to help operationalize these terms for PCORnet® CRNs.[6] This led to the formation of the PRO Common Measures Work Group, which developed a group of eight "core" and six highly recommended PRO domains for adult and pediatric patients (see Table 1). The work group also developed a list of recommended single items that correspond with each domain, with most items taken from the Patient-Reported Outcomes Measurement Information System (PROMIS®).

Table 1. PRO Common Measures

Domain Set	Domains Included
Adult Core Domains	Pain, fatigue, depression, sleep, physical function, social function, and general (global) perceptions of health and life quality
Pediatric Core Domains	Pain, fatigue, depression, stress, peer relationships, family relationships, and general (global) perceptions of health and life quality
Highly Recommended	Global physical health, global mental health, anxiety, treatment adherence, experience of care (treatment satisfaction), and life satisfaction

In Phase 1 of PCORnet, CRNs were required to collect these PRO common measures.[7] However, PCORnet® CRNs found this limited set to be too restrictive and raised concerns that the common measure set had reduced usability because they represented individual items selected from multi-item scales.[8] While PCORnet® CRNs found that incorporating PRO data elements into the PCORnet® CDM was not

The PCORnet® CDM PRO table includes a range of fields for PRO data elements:

- Name of the PRO item and PRO measure (if item is part of a measure)
- Logical Observation Identifiers Names and Codes (LOINC®) code for PRO item
- Version of the item and measure
- Text for the PRO item question
- Text version of the response
- Method of administration
- Self or proxy report
- Raw and standardized scores for measure (if item is part of measure)

challenging, they did cite difficulties regarding EHR integration, which impacted ability to extract and transform data. PCORnet® CRNs also cited difficulties engaging patients in completing PRO measures (administered via surveys).[9]

Initially, the PCORnet® CDM allowed for the inclusion of the limited set of PRO common measures.[10] In 2018 (CDM V4.0), the PCORnet® CDM specification was modified to allow for storing of a range of PRO measures in the PRO Common Measures (CM) table. Currently, the PCORnet® CDM (V6.0) allows for the capture of individual item-level responses and overall scores for a measure/instrument. The PCORnet® CDM PRO Common Measures (PRO-CM) table is defined to support a range of possible use cases. As a result, values may be duplicated across records and others may have blank fields.[11]

1.2 Roadmap of Paper

The paper begins with a brief overview of NORC's research methods, followed by key findings which are separated by PROs and other PGHD. For each, the findings first describe the current state of data collection within health systems participating in PCORnet, based on a survey fielded in September 2021. Next, using information from key informants and additional resources, this paper discusses current challenges related to PROs and PCORnet infrastructure, as well as potential short-, mid-, and long-term opportunities to address these challenges. The next section focuses on the challenges and opportunities associated with incorporating and leveraging PGHD given the current state of its collection across PCORnet® CRNs. Finally, we review relevant initiatives that exist in parallel to the PCORnet ecosystem and will advance the standardized collection and use of PROs and PGHD.

The intended audience for this paper includes PCORI staff, the PCORI Board of Governors, the Coordinating Center for PCORnet, PCORnet® CRNs, and the broader research and stakeholder community interested in opportunities to enhance health system infrastructure and research capabilities for use of PROs and PGHD.

These findings are intended to assist PCORI in assessing and prioritizing opportunities to enhance PCORnet in alignment with the PCORI Board of Governors-approved *Prioritizing Principles for Infrastructure Funding Relating to PCORnet*.[12]

2. Methods

Four data collection activities informed this White Paper:

1. A survey of 53 health systems that are part of PCORnet® CRNs regarding the current state of their PRO and PGHD data collection and use;
2. A targeted literature review focused on PCORnet® CRNs' PRO and PGHD infrastructure, as well as challenges and opportunities within the PRO space;
3. Interviews with nine key informants of PCORnet® CRN leaders, members of PCORI's Board of Governors, and external PRO and PGHD and data infrastructure experts.
4. A 90-minute public webinar on the White Paper findings to gather a broad set of perspectives from presenters and attendees on opportunities to enhance PRO and PGHD data infrastructure across PCORnet® CRNs.

Appendix C. includes further expands on the details of the methods.

3. Key Survey Findings

In section 3.1, we present the results of our research in two sections: 1) current state of PRO data collection and use across PCORnet® CRNs and 2) challenges and opportunities for PRO availability and accessibility across PCORnet® CRNs. In section 3.2, we present the results of our research focused on PGHD, organized by 1) current state of PGHD collection and use within PCORnet® CRNs and 2) challenges and opportunities for PGHD use for research.

3.1 Current Landscape of PRO Data Capture and Use Across PCORnet® CRNs

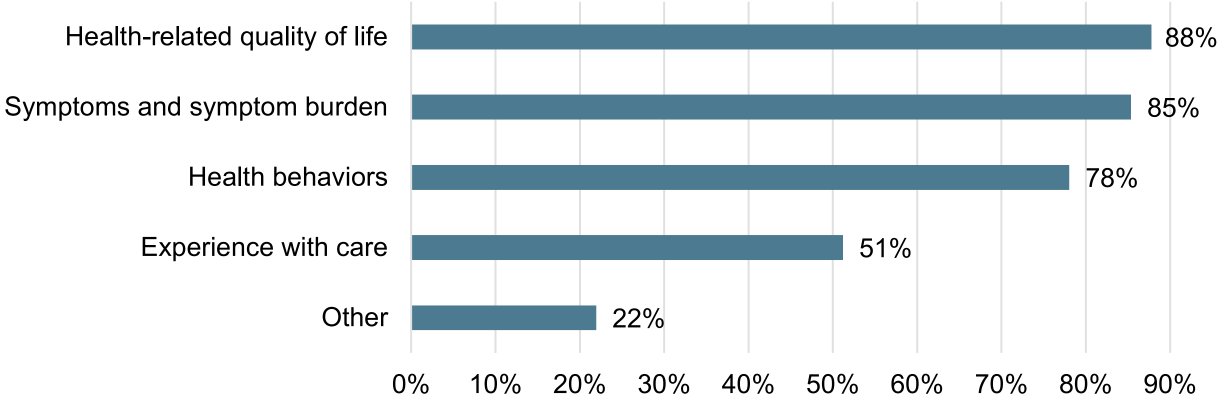
The survey provided an understanding of the current landscape of PRO data capture and use among 53 out of 75 health systems participating in PCORnet. The survey results informed our conversations with key informants and our literature review.

Most health systems are collecting PROs as part of clinical care. The survey asked health systems if they are currently collecting PROs as part of clinical care and to what extent across their clinical specialties. Seventy-eight percent (n=41) of health systems responded that they are currently collecting PRO data, while 13 percent are not currently collecting PROs as part of clinical care and 9 percent of health systems are unsure.

Thirty-eight percent of health systems report that they are currently collecting PROs in most clinical specialties, while 40 percent are currently collecting PROs in some but not most clinical specialties. Health systems frequently identified behavioral health (76 percent), pediatrics (71 percent), internal medicine (68 percent), and orthopedics (56 percent) as clinical specialties that collected PROs as part of clinical care.

If a health system reported that they were currently collecting PRO data, the survey prompted them to indicate which domains of PROs their health systems collect. Most health systems reported collecting data on health-related quality of life and symptoms/symptom burden. Other common domains included health behaviors and experience with care (see Figure 2).

Figure 2. PROs Domains Health Systems are Collecting (n = 41)



Most health systems currently collecting PRO data are using the PROMIS® measure set. For health systems that currently collect PRO data, the survey asked respondents to specify which measure sets and specific measures they are using to collect PROs as part of clinical care. Health systems most frequently reported using the PROMIS measure set (78 percent), followed by HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) (34 percent) (see Appendix C Table C-1). Identifying the specific measures collected within health systems is unclear. When asked to list additional PRO measures their health system is using as part of clinical care, about 43 percent of health systems answered they were not aware of which specific measures were being collected. Other responses identified multiple PROMIS measures (n=14) including mental health (n=4) and quality of life (n=3).

When asked to list additional PRO measures used, respondents reported nearly 500 measures. The most frequent measures reported included PHQ-9 (Patient Health Questionnaire-9) (n=15), PHQ-2 (Patient Health Questionnaire-2) (n=8), GAD-7 (General Anxiety Disorder-7) (n=7), AUDIT (Alcohol Use Disorders Identification Test) (n=5), M-CHAT (Modified Checklist for Autism in Toddlers) (n=3), activities of daily living, and behavioral health screening tools (Table 2). Health systems affiliated with seven CRNs report collecting the PHQ-9.

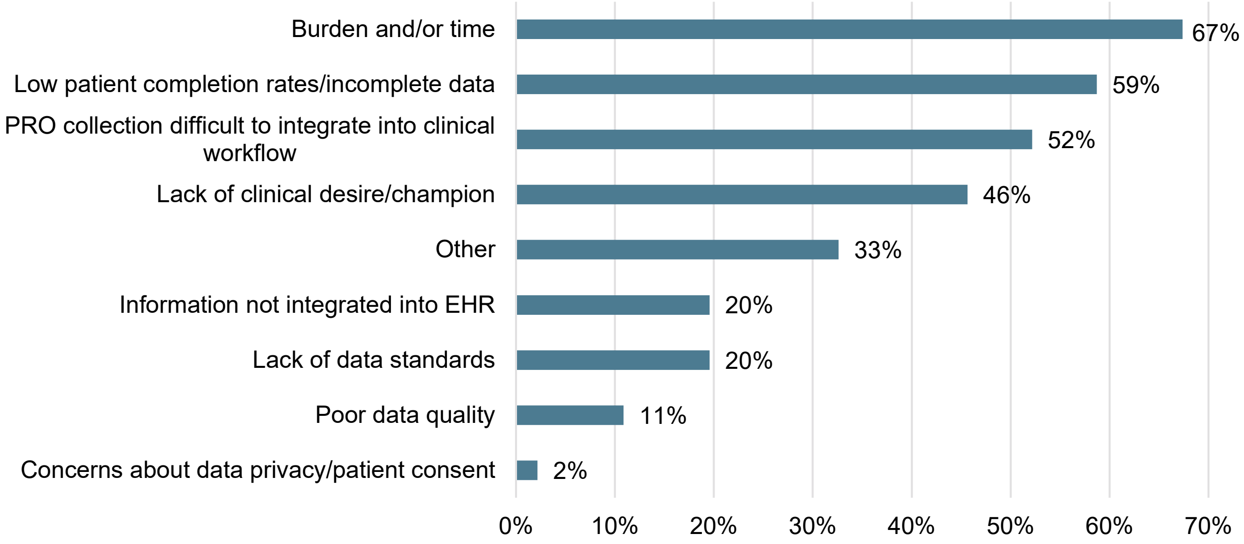
Table 2. PROs Measure Sets Used by Health Systems Currently Collecting PROs (n = 41)

Measure Set*	Health Systems Indicating Use
PROMIS	78%
HCAHPS	34%
Neuro-QoL	20%
NIH Toolbox	10%
ASQC-Me	2%
PRO-CTCAE	0%
None of the Above	12%

*Respondents could select more than one measure set.

The most frequent challenge for health systems in collecting PROs is burden and time. For both health systems currently collecting PRO data and health systems that were unsure of what PRO data they are collecting, the survey asked what challenges they have encountered when implementing PRO collection and use in clinical care. The most frequently selected response was burden and/or time for collecting PROs in clinical care (67 percent), followed by low patient completion rates/incomplete data (59 percent) (see Figure 3). In the context of the survey, "burden" is described as the amount of effort to collect PROs in clinical care.

Figure 3. Challenges to PRO Collection for Health Systems Currently Collecting PROs (n = 46)



Forty-eight percent of health systems that currently collect PRO data reported these data are fully integrated into their EHR*.* The survey asked health systems to specify to what extent PROs are integrated into their health system's EHR, from "full integration" to "no integration". Full EHR integration includes the collection of computable data in the EHR that can be plotted along other data collected in the EHR. No EHR integration would mean that PRO data are collected through paper forms. The most frequently selected option was full integration (48 percent). Another 28 percent answered that their system has mixed EHR integration (i.e., some computable collected in the EHR and paper form). The types of PRO measures collected via EHR versus other formats was not captured by the survey.

When asked respondents to describe their health systems' plans for collecting and using PROs in the next 2 to 4 years; health system responses generally fell into four categories:

- ***Planning to expand PRO collection*****.** These included responses of expanding PRO collection to additional clinical specialties and improving processes for collecting PRO data to reduce patient burnout.
- ***Integrating PROs into the EHR.*** One health system shared that they are undergoing efforts to convert paper to electronic forms to ensure data are integrated in the EHR for research and quality improvement.
- ***Making PRO data available for research and integrating PROs into the EHR***. One health system expanded on this point by indicating they wanted to ensure their data are more accessible.
- ***Not aware of health system plans.*** Roughly a third of respondents are not aware of their health system's plans for PRO collection.

In summary, we identified three salient themes across survey responses related to PROs:

- While most health systems report they are collecting PRO data, the extent to which this data is fully integrated into the EHR greatly varies.
- Nearly a third of health systems report plans to expand PRO collection within the next 2 to 4 years.
- The majority of health systems collecting PRO data report using PROMIS measures; however, the extent to which there is a single common PRO measure used across health systems is murky. Collectively, health systems indicated they were collecting nearly 500 distinct PRO measures, with limited overlap in measures across health systems.

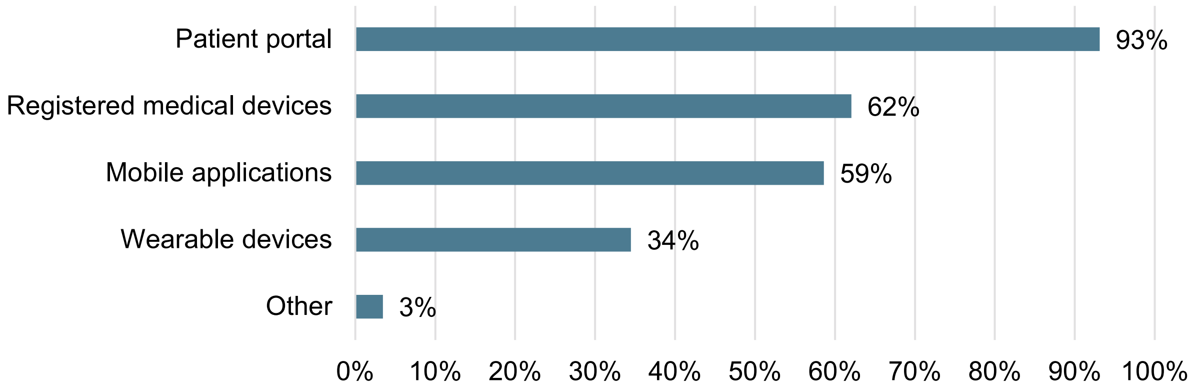
3.2 Current Landscape of PGHD Capture and Use within Health Systems Participating in PCORnet

In addition to providing additional insight into PROs, the survey provided a lens into the extent to which PGHD is currently being captured within health systems participating in PCORnet.

Fifty-five percent of health systems indicated that they are currently collecting PGHD, while 32 percent reported that they did not know, and 13 percent reported they were not collecting PGHD. Almost all health systems that reported collecting PGHD are using patient portals to capture this data. Other common sources of PGHD included registered medical devices and mobile applications (see Figure 4).

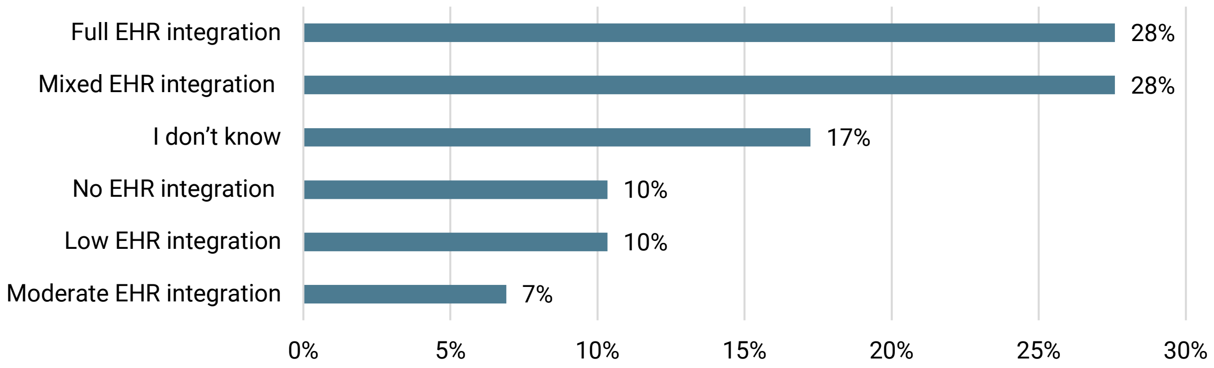
The survey then asked health systems to indicate the types of PGHD they are collecting. The most frequently selected types included biometric data (69 percent), symptoms (69 percent), and health history (69 percent).

Figure 4. Health Systems' Sources of PGHD for those Currently Collecting PGHD (n = 29)



Roughly one-third of health systems currently collecting PGHD report full EHR integration of PGHD. Of the 29 health systems currently collecting PGHD, eight reported that PGHD was fully integrated into the EHR (28 percent of those collecting PGHD). An additional eight reported mixed EHR integration (28 percent of those collecting PGHD). About 17 percent of health systems collecting PGHD reported they did not know the extent to which the data are integrated into their health system's EHR (Figure 5).

Figure 5. PGHD EHR Integration for Health Systems Currently Collecting PGHD (n = 29)



The survey included an optional question asking about health systems' plans for collecting PGHD in the next 2 to 4 years. Roughly 60% of question respondents referenced expanding PGHD collection in some way. The data collection methods most referenced were remote patient monitoring and wearable devices.

To summarize, many health systems are still at a nascent stage of PGHD collection, with limited EHR integration. Health systems that are collecting PGHD are primarily collecting these data through patient portals and most commonly collecting biometric data, symptoms, and health history. Multiple health systems report having plans to expand PGHD collection within the next 2 to 4 years.

4. Challenges and Opportunities to Enhancing PROs and PGHD Data Infrastructure for Research

4.1 Challenges and Opportunities: PRO Use for Research Purposes

Below, we draw from the literature, KIIs, and webinar feedback to identify challenges and opportunities for increasing the availability and accessibility of PRO data within PCORnet® CRNs through data infrastructure enhancements. Challenges and opportunities arose in three areas:

- Engaging stakeholders on PRO data priorities for the PCORnet® CDM, clinical care, and research.
- Leveraging PRO data collected as part of routine clinical care.
- Facilitating the loading and use of PRO data collected during research.

Engaging Stakeholders around PRO Data Priorities for the PCORnet® CDM, Clinical Care, and Research

Key informants suggested that PCORI consider opportunities for enhancing PRO data capture through stakeholder engagement in addition to the engagement that occurs for each PCORnet-enabled study.[13] Key informants raised two areas where further engagement may be complementary to data infrastructure projects: 1) engaging PCORnet® CRNs and other stakeholders around the value of collecting PRO data and 2) convening PCORnet Network Partners to stabilize mapping procedures of PRO fields in the PCORnet® CDM.

Challenge 1: Lack of uptake in PRO data collection and capture in the PCORnet® CDM. To be valuable in research, PRO data must be meaningful to patients and other stakeholders. PROs must also be aggregated, standardized, and curated for research. While many health systems and CRNs are collecting PRO data, both key informants and webinar participants noted that the uptake of PRO data collection remains limited. The survey found that some health systems were not actively collecting PROs at the time. Furthermore, even if PROs are collected, the data may not be captured within the PCORnet® CDM. These findings indicate that the overall value of collecting PRO data within research and clinical settings and capturing this data in the PCORnet® CDM may be unclear to health systems.

Opportunity 1: Engaging PCORnet® CRNs and other stakeholders around the value of collecting PRO data as part of clinical care for downstream use in research (Short-term). Key informants recommended broader discussions across PCORnet Network Partners regarding the value of collecting PRO measures as part of clinical care and capturing these PRO data within the PCORnet® CDM for research. In particular, there is a need to improve understanding among stakeholders of the shared value proposition between PCORnet, patients, clinicians, and health systems in the collection and use of PRO data for clinical care and research. These conversations may also be an opportunity to identify PRO measures that are both primed for standardization and meaningful to patients, clinicians, and other stakeholders. During the webinar, audience members also emphasized the need to engage patients in PRO collection and use, and specifically identify PROs that were meaningful patients.

Challenge 2: Inconsistent mapping of PRO data elements to fields in the PCORnet® CDM PRO-CM table. The PCORnet® CDM provides information regarding the meaning of each PRO data field; however, key informants stated that study investigators and their teams lack a shared understanding of how PRO data should be mapped. For example, in documenting the PRO measure used, some study teams may use the "PRO measure name" field while other study teams may place the same information under the "PRO measure text" field. Key informants from PCORnet® CRNs shared that study investigators and their teams may require multiple conversations to ensure that PRO data elements are consistently loaded in the same PCORnet® CDM fields of the PRO-CM table across health systems. Reconciling PRO data for each study can be time consuming and create delays in timelines for research completion.

Opportunity 2: Engage PCORnet® CRNs and other stakeholders to stabilize Network mapping and loading procedures for the PCORnet® CDM PRO-CM table (Short-term). Additional conversations about how to place information within the PRO-CM table in the PCORnet® CDM could create efficiencies for study investigators and support PRO data capture. While enhancing resources to populate and refresh the PRO-CM table are important, as described in a later opportunity below, a key step in this process would be to convene PCORnet® Network Partners to discuss Network procedures for how they should map data to the PRO-CM table and, in the process, identify and remediate inconsistencies across sites and health systems. This may have the potential to create efficiencies for study investigators and support PRO data capture. A shared understanding of how to map PRO data elements in the PCORnet® CDM could also reduce the validation processes for individual research efforts.

Leveraging PRO Data Collected as Part of Routine Clinical Care

The capture and standardization of EHR data from PCORnet® CRNs is an important facet of the mission and vision of PCORnet.[14] In discussing the prospect of leveraging PRO data from EHRs, key informants noted this is a developing area for PCORnet® CRNs. The survey results showed that several participating health systems are exploring how to routinely collect PROs as part of clinical care and integrate these data into the EHR. Implementing routine PRO collection is a complex process that is dependent on institutional capabilities and the EHR platform/vendor, and typically involves a range of stakeholders (e.g., clinicians, legal affairs, health information technology).[15] Key informants suggested that routine capture of PRO data from EHRs in the PCORnet® CDM is impeded by a range of factors including the heterogeneity of PRO measures collected, capabilities of EHR platforms, and processes for standardizing data.

Challenge 3: Heterogeneity in practices around PRO data across PCORnet® CRNs and health systems. The survey findings indicated that across health systems participating in PCORnet, there is some volume of PRO data that are integrated within the EHR. To date, the majority of these data have not been standardized using the PCORnet® CDM and are not readily available in CRN DataMarts. Three challenges related to heterogeneity in practices across CRNs and health systems for capturing PRO data were identified in the course of our information gathering.

3a) The heterogeneity of PRO measures collected across health systems and PCORnet® CRNs. The survey found that there are some commonly measured PRO domains collected across health systems participating in CRNs. A majority of health systems collecting PROs are using PROMIS measures and several health systems are collecting the PHQ-9; however, overall, there are a variety of PROs collected by health systems. As the survey showed, nearly 500 distinct PRO measures are collected across health systems participating in PCORnet.

> **"One of the things that we found [is] that people have a versioning issue. One version of the instrument, even if it is supposed to be standardized, could change the option choices and subsequent logic over time, so even if the instrument had the same name, it wasn't the same version."**
>
> - Key Informant, PRO Data Infrastructure Expert

The collection of PRO measures is often specific to a clinical area, with some disciplines like oncology or orthopedics more frequently collecting PRO measures than others. During the webinar, speakers noted that some clinical specialties like cardiology may focus on collecting data clinical endpoints (e.g., mortality) while others like orthopedics tend to focus more on the collection of PROs like functional outcomes. Key informants also noted that PRO collection is often dictated by health system priorities, quality improvement efforts, or specific policy initiatives and incentives (e.g., the Bundled Payments for Care Improvement initiative).

3b) Heterogeneity of site-specific implementation of commonly used instruments. In addition to the challenges associated with having numerous heterogeneous measures to collect PROs, variability also arises when health systems and their sites use different versions or make site-specific modifications to questionnaires/instruments. While many PRO measures are validated and standardized, this variability across sites will require additional data harmonization as response choices can be different across different versions of instruments.

In terms of standardizing PRO collection within the EHR and reducing variability, there have been advancements related to the use of certain measure sets for some vendors. For example, Epic provides an option to activate

> **"When you go into MyChart, we collect 12,000 distinct PROMIS measures. We have like 15 versions of PROMIS now. There is a committee that tries to keep some control on what's implemented, but there are still repeats and overlap."**
>
> - Key Informant, PCORnet® CRN Leader

PROMIS instruments as part of its standard implementation, and PROs can be collected from patients directly through the MyChart patient portal. Epic seems to be one of the few EHR vendors that have integrated PRO questionnaires into the EHR.[16] Epic also allows for the native mapping to terminology standards for instruments that have LOINC codes such as PROMIS.[17] However, PRO questionnaires may differ across different versions of Epic, impeding standardized collection. During the webinar, speakers shared an example of a study using the Kansas City Cardiomyopathy Questionnaire. While all three participating sites used Epic, there was variation in the instruments across sites, which impeded the standardized collection of data.

For EHR systems that do not have integrated PRO questionnaires, SMART on FHIR (Fast Healthcare Interoperability Resources®) apps can be used to collect PROs via the patient portal or using iPads in clinics. This contributes to the variability in PRO questionnaires used and the heterogeneity of PRO data. Key informants stated that integrating the collected PRO data into the EHR requires complex workarounds. Third parties like the Electronic Health Record Access to Seamless Integration of Patient-Reported Outcomes (EASIPRO) initiative have advanced tools and software to support the integration of PRO data within widely used EHRs, including Epic and Cerner.[18] However, workarounds to get PRO data into the EHR often require custom implementations for each site. In addition, this requires that each site manually map data to LOINC or other standardized terminologies, which can be resource-intensive.

3c) Heterogeneity of processes and workflows for capturing and loading PRO data in the PCORnet® CDM. While PRO collection is highly variable, there is potential value in capturing PRO data from EHRs and standardizing them within the PCORnet® CDM. This requires local development of extract, transform, load (ETL) processes to capture and load the data into the PCORnet® CDM. In the context of PRO data, ETL processes are often developed by health systems on a study-specific basis. Key informants indicated that while developing ETL processes can be complex, a significant barrier to the standardization of PRO data within the PCORnet® CDM is a lack of incentive to proactively build these processes and capture available PRO data for research use.

Opportunity 3: Conduct additional analysis to identify commonly used PRO measures and data practices across PCORnet that can be standardized and leveraged Network-wide (Short-term). The extent to which there are common PRO measures collected across CRN sites is unclear. In addition, while PRO measures are often validated and standardized, health systems may use different versions or modified versions of the same instruments. Furthermore, capturing PRO data from EHRs in the PCORnet® CDM requires local development of ETL processes. To address these barriers, findings indicate a multi-pronged opportunity across PCORnet Network Partners to:

- Conduct additional surveillance efforts to determine the full range of PRO measures collected by PCORnet® CRNs as part of clinical care to then determine common measures. Given that PRO collection is often dictated by policy initiatives and incentives, commonly collected measures may exist within certain disciplines or clinical areas (e.g., orthopedics, oncology, behavioral health).
- Examine the extent to which question and response strings differ across sites for commonly used PRO measures. This would inform the standardization of a subset of PRO instruments across PCORnet® CRNs. Webinar audience members suggested that measures that reflect the life issues that are of most concern to the patients (e.g., quality of life measures) should be considered for standardization. Multiple webinar audience members added that patient panels are important to determine appropriateness of and to prioritize PRO measures.
- Support the development of processes and workflows for capturing the standardized PRO measures in the PCORnet® CDM for specific use cases. Key informants suggested that potential use cases could include PRO measures for oncology, orthopedics, and behavioral health. This would build capacity for PRO data capture within the PCORnet® CDM.

Challenge 4: Complexity making PRO data captured from the EHR “research ready.” The Coordinating Center for PCORnet has established processes for ensuring the quality and completeness of data within the PCORnet® CDM. Data quality checks occur in a two-stage process, first checking for conformance, completeness, plausibility, and persistence in the first stage, followed by research readiness in the second phase.[19,20] The second phase of data curation is study specific, and ensures that data are fit-for-purpose for a specific analysis.[21] The majority of PRO data collected by sites is not loaded into PCORnet® CRN DataMarts, meaning that these data are not available across the CRN sites and do not undergo data quality checks. For the few PCORnet® CRNs where PRO data are in the PCORnet® CDM, these data are not examined on a granular level until a specific query is distributed to DataMarts by the Coordinating Center.[22] Consequently, the research readiness of PRO data available in DataMarts is unclear until a query is submitted.

There may be several challenges related to data curation of PRO data once a query is submitted. First, there can be differences in the latency of data. PCORnet® CRNs refresh their CDMs quarterly and run data quality assessments with each refresh.[23] However, key informants shared that the timing of these refreshes can vary and that there can be months-long differences in latency between sites (e.g., a 3-month lag versus a 6-month lag). Second, there may be discrepancies in whether sites provide item-level scores or summary scores. If item-level scores are not provided, they must be manually generated based on text responses. Likewise, summary scores may need to be manually generated if sites only provide item-level responses. Finally, there are discrepancies in the use of the PCORnet® CDM PRO table. Sites can put the same PRO data elements in different fields of the PCORnet® CDM. Reconciling these differences after the query is submitted increases the time burden for researchers.

Opportunity 4: Enhance resources for PCORnet data curation processes around expanded PRO data elements in the PCORnet® CDM (Mid-term). Additional steps can be taken to ensure PRO data are research ready in the PCORnet® CDM, such as providing resources to populate and refresh the PRO-CM data table. While current PCORnet quarterly data curation processes do not require DataMarts to load data into the PRO-CM table of the PCORnet® CDM, quality checks for “research readiness” do not occur until a relevant, study-specific query (i.e., research question) is submitted to CRNs by the Coordinating Center for PCORnet. During the webinar both speakers and audience members also emphasized the importance of including both item-level and total scores when reporting PROs. By providing additional resources to support “research ready” PRO data, the latency of PRO data may be lowered, and the quality may be increased, thus supporting increased use of item-level scores or summary scores in the PRO-CM table of the PCORnet® CDM.

Facilitating the Loading and Use of PRO Data Collected During Research

Key informants emphasized that PCORnet® CRNs serve as venues for prospective research and that most opportunities for PRO capture were related to prospective data collection. While EHRs and patient portals may be used for data collection during research, key informants noted that it may be difficult to receive approval from Institutional Review Boards to administer a questionnaire for research using these methods. During the webinar, speakers noted that using EHRs for research may require workarounds if PRO data are not already fully integrated into the EHR. Given these limitations, researchers may use third-party platforms (e.g., REDCap, Qualtrics) separate from EHRs to administer questionnaires and collect PRO data prospectively during clinical studies.

Key informants suggested that future data infrastructure efforts should consider how to support the standardized collection of PROs via third-party tools and how to advance processes for loading the PRO data into the PCORnet® CDM.

Challenge 5: Variability in study-specific PRO questionnaires deployed by research teams using PCORnet. For research studies, PRO data are often collected via platforms such as REDCap, with research teams developing study-specific data dictionaries and PRO instruments. For scope, REDCap's library of data collection instruments and forms that can be used by researchers contains over 2,000 instruments including PROMIS®, ASCQ-Me®, and Neuro-QoL CATs, and yet it is not an exhaustive resource for PRO measures.[24,25] For the development of study-specific questionnaires, REDCap and other similar platforms may support the use of a common data dictionary, ensuring that PRO instruments are identical across participating research sites even when using separate instances of the same platform to try to minimize variability.

Despite the use of common PRO platforms, study-specific data dictionaries and the myriad PRO instruments may nonetheless introduce heterogeneity in the way PROs are collected. Arising from the clinical care challenges described previously, each study may make modifications to their measure response items, which creates heterogeneity in the measures that are being collected. This variability of questionnaires has downstream impacts in terms of the ability to standardize PRO data collected prospectively through third-party platforms.

Opportunity 5: Work with CRNs to develop a repository of PRO questionnaires for researchers to use in studies that use PCORnet (Mid-term). Given the variability introduced by numerous standardized instruments and study-specific questionnaires, the Coordinating Center for PCORnet could support the development of a repository of PRO instruments that are importable within survey platforms like REDCap and Qualtrics. This effort would initially need to focus on a small set of measures that appear to be used consistently or frequently across research studies, such as the PHQ-9, before expanding to a more comprehensive repository of PRO questionnaires. As part of developing the repository, the Coordinating Center for PCORnet would need to engage PCORnet® CRNs to determine what existing study-developed questionnaires are available and to what extent they are primed for wider use by investigators.

During the webinar, speakers noted a standardized questionnaire bank, similar to that which REDCap offers, would make it easier for CRNs to standardize and transfer their PRO data to the PCORnet® CDM. However, researchers often have preferred instruments and administration methods they use for their studies; therefore, reconciling this issue within this opportunity would be important.

Challenge 6. PRO data collected during research are not currently loaded into the PCORnet® CDM. While PRO data are collected via third-party platforms (e.g., REDCap) for a range of studies, these data are usually not standardized and loaded into

PCORnet® CRN DataMarts. Key informants suggested that PRO data from REDCap are not put into the PCORnet® CDM due to two factors: 1) researchers are used to their existing workflows and 2) executing site-specific ETL processes are resource intensive.

Key informants stated that researchers using PRO data may not fully understand the value of the PCORnet® CDM. Research teams have established workflows for collecting and analyzing PRO data from EHRs, REDCap, patient portals, other survey tools, etc. Researchers lack incentives to convert PRO data collected via other platforms into the PCORnet® CDM. Key informants suggested that this may be especially true for small or moderately sized research studies where there is not a need to standardize a large volume of data across multiple sites.

> **"Study teams are used to interacting with patients and saving their data separately; they are not used to a workflow where the data is entering the CDM. That matters in the context of standardization and usefulness of the data. If that data is not standardized, there are questions about its validity, and it is seen as less valuable. The barrier isn't a structure; it is the perceived value of having data in the CDM."**
>
> \- Key Informant, PCORnet® CRN Leader

Additionally, establishing workflows and executing ETL processes for capturing PRO data at the site-level will be highly dependent on local informatics expertise and resources.[26] Some PCORnet® CRNs have piloted solutions to facilitate ETL of PRO data from third-party platforms into the PCORnet® CDM. For example, PaTH previously leveraged the REDCap application programming interface (API) and developed open-source software to support the consistent extraction of REDCap PRO data into PCORnet® CDM v4.1.[27]

Opportunity 6: Identify data infrastructure supports locally (i.e., for participating health systems) for PRO data collection for PCORnet studies (Short-term). Data infrastructure projects focused on capturing third-party platform PRO data must consider both the technical aspects of creating an infrastructure and the need to incentivize researchers to change their workflows and use the PCORnet® CDM. In the short-term, the Coordinating Center for PCORnet could develop plug-ins for third-party survey/questionnaire platforms that could be locally installed. This would allow for the simultaneous updates of instruments across sites and establish consistency throughout PCORnet® CRNs for those that are using these platforms. However, sites that do not have existing instances of these platforms would likely encounter challenges. Key informants shared that third-party platform implementation for survey/questionnaire administration is costly, resource intensive, and requires buy-in and participation from multiple stakeholders within each site.

Opportunity 7: Explore centralized data infrastructure and services (i.e., across the PCORnet® CRNs) for PRO data collection (Long-term). In the long-term, the Coordinating Center for PCORnet could consider how to create efficiencies in the use of third-party data collection platforms by establishing centralized services for PRO data collection in studies that use PCORnet. A centralized structure would support standardized collection of PRO data and seamless ETL of data from the platform(s) to the PCORnet® CDM. However, using a centralized structure may make it difficult to upload patient identifiers and link survey/questionnaire data to EHR data. Sites may encounter resistance from Institutional Review Boards to share patient identifiers with the Coordinating Center for PCORnet due to concerns about patient privacy. To mitigate this, sites would have to either establish processes to obtain patient consent to send identifying information to the centralized system or establish post-hoc identification processes to reconcile identifiers from third-party administered survey/questionnaires with information in the EHR.

Webinar speakers suggested that implementing PRO data standards across PCORnet® CRNs could assist with more standardized PRO data collection and easier integration into the PCORnet® CDM, creating a bridge between central and local infrastructure. They referenced the Lister Hill National Center for Biomedical Communications (LHC) Fast Healthcare Interoperability Resources® (FHIR) tools[28], which could be a starting point for developing standardized PRO collection processes.

4.2 Challenges and Opportunities: PGHD Use for Research Purposes

The results of the survey indicate that PGHD is not widely collected or used by the PCORnet® CRNs, meaning that PCORnet is at the initial stages of engagement with PGHD. Given this current state, the literature, KIIs, and webinar point to the need to set priorities for PGHD and enhance PCORnet infrastructure accordingly.

Enhancing PCORnet Data Infrastructure to Load and Leverage PGHD for Research

The capture, use, and standardization of other PGHD—specifically from wearables, medical devices, and patient portals—is still in an emergent stage across PCORnet® CRNs. The survey found that several health systems participating in PCORnet® CRNs see increased capacity for the capture and integration of PGHD as a broader goal for their system.

Challenge 1: Enhancing PCORnet data infrastructure to leverage PGHD for research. The PCORnet® CDM currently does not support the capture of PGHD collected from patient portals, wearable devices, and registered medical devices. Key informants suggested that the Coordinating Center for PCORnet consider piloting modifications to the PCORnet® CDM that support the capture of certain types of PGHD from wearable devices. If successful, then this could spur enhancements to the PCORnet® CDM such as additional PGHD data elements and/or tables to support data collection. However, given that interoperability standards for capture and use of PGHD are immature, broader advancements beyond the PCORnet ecosystem are needed to support the integration of PGHD from sources like wearable devices into the EHR.[29,30,31] During the webinar, speakers indicated that existing third-party data collection platforms may support the collection and use of PGHD in research separate from the PCORnet® CDM.

Opportunity 1: Explore what platforms and technologies PCORnet Network Partners use to collect PGHD (e.g., apps, portals, EHRs, third-party, etc.) (Short-term). The collection, use, and standardization of other PGHD—specifically, data from wearables, medical devices, and patient portals—is still in an emergent stage across PCORnet® CRNs. Existing platforms can facilitate use of PGHD for research across the CRN sites by supporting the collection of PGHD and allowing for this data to be linked to data from PCORnet® CRNs; however, the types of platforms and technologies used and their performance across the Network is relatively unknown.

During the webinar, speakers highlighted the Eureka Research Platform as a way to facilitate the collection of PGHD in research. The platform is currently in use for PCORnet designated studies and studies that use the infrastructure of PCORnet, including a large blood pressure study funded by the National Institutes of Health, where patients were recruited to the study using EHR-based targeting and invitations.[32,33] A more in-depth exploration of the types of platforms and technologies that Network sites use to capture PGHD and understanding what PGHD sites access would inform the development of upgrades to the PCORnet® CDM for loading PGHD from various sources.

Opportunity 2: Pilot modifications to the PCORnet® CDM that support the capture of certain types of PGHD (Mid- and Long-term). The survey found that several health systems participating in PCORnet® see increased capacity for the capture and integration of PGHD as a broader goal for their system. Piloting modifications to the PCORnet® CDM would support the capture of PGHD —starting with the inclusion of dedicated fields for promising use cases (e.g., home blood pressure machines, glucometers) (Mid-term). These modifications to the PCORnet® CDM around PGHD should align with the emerging FHIR standards in this field, which is a longer-term opportunity. Depending on the success of the PCORnet CDM pilots, the Coordinating

Center for PCORnet could consider developing and piloting a separate PGHD table in the PCORnet® CDM that allows for the capture of range of PGHD from wearables and Bluetooth-enabled medical devices (Long-term). During the webinar, speakers noted that interoperability standards for mobile health data such as Open mHealth could be used to inform updates to the PCORnet® CDM.

Conclusions

The findings of our literature review, KIIs, and webinar surfaced seven challenges and nine opportunities for the capture of PROs and PGHD that represent areas for PCORI's consideration in the short-, mid-, and long-term. Enhancing the availability of PRO data and PGHD in the PCORnet® CDM and improving the informatics capabilities and Network engagement to capture these data will support PCORI's Phase 3 goal of using PCORnet to conduct definitive national studies that advance PCORI's National Priorities for Health, including efforts to accelerate progress towards a learning health system and ensure an ecosystem of PROs and PGHD to support the next generation and innovation of PCOR studies.

The challenges and opportunities for PROs fall into three major themes: 1) leveraging PRO data collected as part of routine clinical care, 2) strategies to facilitate the loading and use of PRO data collected during research, and 3) engaging stakeholders around PRO data priorities. In the short term, opportunities for PRO data within the EHR are focused on identifying common PRO measures used by sites in clinical care and supporting the standardization of these measures. Key informants also recommended focusing on promising use cases to capture PROs from EHRs in the PCORnet® CDM. Opportunities for better leveraging PRO data collected during research are focused on enhancing capabilities within each site's local environment.

Key informants suggested that there may be long-term opportunities to develop centralized structure and services for the collection of PROs; however, webinar participants emphasized the importance of local infrastructure as there is no "one size fits all" approach across PCORnet® CRNs and participating sites. While considerations for enhancing capacity to leverage PGHD for research will be dependent upon advancements in PGHD standards development, in the short-term, research studies may be able to leverage third-party platforms to facilitate the collection of PGHD. As PCORI considers areas for potential data infrastructure enhancements across CRN sites, there are opportunities to engage patients, to ensure that use cases and standardized questionnaires reflect what is most meaningful to them.

Appendix A. PRO/PGHD Survey of PCORnet Participants

Thank you for your efforts in responding to the earlier survey on SDOH data. As we continue to examine ways in which PCORnet data infrastructure can be enhanced, we are now asking for information related to the collection of patient-reported outcomes (PROs) and other patient-generated health data (PGHD).

This survey will take less than 15-20 minutes to complete. The purpose of this survey is to understand the current landscape within the Network in the area of collecting and integrating PROs/PGHD data. The results of the survey will be shared with PCORI and will be used to inform qualitative data collection for a PROs/PGHD White Paper and webinar which will ultimately inform the strategic planning process.

For this survey, we define PRO and PGHD as follows:

- PRO: A measurement based on a report directly from the patient (or their designated proxy) about the status of a patient's health condition without amendment or interpretation of the patient's response.[8]
- PGHD: Health-related data created, recorded, or gathered outside a clinical setting— through a mobile application, device, or patient portal—by or from patients (or family members and other caregivers).[9]

We recognize that there is often variation within health systems in PRO and PGHD collection. You may need to consult with others in your health system to answer our questions. We ask that you complete the questions to the best of your knowledge.

Section 1– Respondent Information

1. Name

2. Role

3. Email Address

4. Name of Affiliated CRN (*Select from dropdown list)*

5. Name of Affiliated Health System

---

[8] Locklear TD, et al. Reaching Consensus on Patient-Centered Definitions: a Report from the Patient-Reported Outcomes PCORnet Task Force. April 2015. https://dcricollab.dcri.duke.edu/sites/NIHKR/KR/Reaching%20Consensus_April_9_2015.pdf

[9] Deering MJ. Issue Brief: Patient-Generated Health Data and Health. Office of the National Coordinator for Health Information Technology. December 2020. https://www.healthit.gov/sites/default/files/pghd_brief_final122013.pdf

Section 2– PROs Collection

The following questions ask about the collection of PROs within your health system. We ask that you complete the following questions to the best of your knowledge.

For this survey, we define PROs as a measurement based on a report directly from the patient (or their designated proxy) about the status of a patient' health condition without amendment or interpretation of the patient's response. [10]

6. Does your health system currently collect PROs as part of clinical care?
   a. Yes, my health system currently collects PROs in most clinical specialties – *Continue to question 7*
   b. Yes, my health system currently collects PROs in some, but not most clinical specialties–
   Continue to question 7
   c. No, to my knowledge my health system does not collect PROs as part of clinical care – *Skip to question 16*
   d. I am unsure of what my health system is currently collecting – *Skip to question 12*

7. Please indicate what clinical specialties are currently collecting PROs as part of clinical care. *Select all that apply.*
   a. Behavioral Health
   b. Dermatology
   c. Geriatrics/Elder Care
   d. Internal Medicine
   e. Oncology
   f. Orthopedics
   g. Pediatrics
   h. Rehabilitation Services/Medicine
   i. Surgery/Surgical Specialties
   j. Transplant
   k. Other (please specify)

8. What domains of PROs does your health system collect?[11] *Select all that apply*
   a. Health-related quality of life (including functional status)
   b. Symptoms and symptom burden (e.g., pain, fatigue)
   c. Experience with care

---

[10] Locklear TD, et al. Reaching Consensus on Patient-Centered Definitions: a Report from the Patient-Reported Outcomes PCORnet Task Force. April 2015. https://dcricollab.dcri.duke.edu/sites/NIHKR/KR/Reaching%20Consensus_April_9_2015.pdf

[11] National Quality Forum. Patient Reported Outcomes. https://www.qualityforum.org/Patient-Reported_Outcomes.aspx

   d. Health behaviors (e.g., smoking, diet, exercise)
   e. Other (please specify)

9. Which of these measure sets is your health system using to collect PROs as part of clinical care? *Select all that apply.*
   a. PROMIS® (Patient-Reported Outcomes Measurement Information System)
   b. ASQC-Me® (Adult Sickle Cell Quality of Life Measurement Information System)
   c. NIH Toolbox® (NIH Toolbox for the Assessment of Neurological and Behavioral Function)
   d. Neuro-QoL™ (Quality of Life in Neurological Disorders)
   e. HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems)
   f. PRO-CTCAE™ (Patient-Reported Outcome version of the Common Terminology Criteria for Adverse Events)

10. For the measure sets selected in Question 9, please list the specific measures your health system is using as part of clinical care.

11. {OPTIONAL} Please list any additional PRO measures (e.g., PHQ-9, WHO-5) your health system is using as part of clinical care. *This question is optional.*

12. To what extent are PROs integrated into your health system's electronic health record (EHR)?[12] *Please select the option that best reflects current capabilities.*
   a. Full EHR integration (i.e., PRO data are fully integrated with other data within the EHR and can be plotted along with other data)
   b. Moderate EHR integration (i.e., PRO data is accessible through EHR via a link to a separate website, with limited customizable views of PRO data in EHR)
   c. Low EHR integration (i.e., PRO data accessible through a separate website, and data are available in EHR as images).
   d. Mixed EHR integration (i.e., Some PRO data are accessible through EHR while other PRO data are collected through paper forms)
   e. No EHR integration (i.e., PRO data collected through paper forms)
   f. I don't know

13. What challenges has your health system encountered when implementing PRO collection and use in clinical care? *Select all that apply*
   a. Low patient completion rates/incomplete data
   b. Poor data quality
   c. PRO collection difficult to integrate into clinical workflow

---

[12] Snyder C, and Wu, A.W., eds. Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Baltimore, MD: Johns Hopkins University. 2017. Funded by Patient-Centered Outcomes Research Institute (PCORI); JHU Contract No. 10.01.14 TO2 08.01.15.

Available at: http://www.pcori.org/document/users-guide-integrating-patient-reported-outcomeselectronic-health-records

    d. Information not integrated into EHR
    e. Lack of clinical desire/champion
    f. Lack of data standards
    g. Burden and/or time
    h. Concerns about data privacy/patient consent
    i. Other (please specify)

14. Please describe how PRO data collected within your health system's EHR are used for research. *If you do not know if your system collects PROs for research, write N/A.*

15. {OPTIONAL} Please use the space below to provide any additional information on your health system's use of PROs. *This question is optional.*

    Skip to question 19 after completing this section

Section 3– Reasons for Not Collecting PROs

These questions are only for respondents who answered "c. No, to my knowledge my health system does not collect PROs as part of clinical care," to Question 6

16. Did your health system previously collect PROs as part of clinical care?
    a. Yes, we previously collected PROs as part of clinical care
    b. No, we have not collected PROs as part of clinical care
    c. I don't know

17. Why is your health system not collecting PROs as part of clinical care? *Select all that apply*
    a. Low patient completion rates/incomplete data
    b. Poor data quality
    c. PRO collection difficult to integrate into clinical workflow
    d. Information not integrated into EHR
    e. Lack of clinical desire/champion
    f. Lack of data standards
    g. Burden and/or time
    h. Concerns about data privacy/patient consent
    i. Other (please specify)

18. {OPTIONAL} Please use the space below to provide any additional information on your health system's use of PROs, including any measures your system previously collected. *This question is optional.*

Continue to question 19 after completing this section

Section 4– PGHD Collection

The following questions ask about the collection of PGHD within your health system. We ask that you complete the following questions to the best of your knowledge.

For this survey, we define PGHD as health-related data created, recorded, or gathered outside a clinical setting— through a mobile application, device, or patient portal—by or from patients (or family members and other caregivers).[13]

19. Is your health system collecting any PGHD?
    a. Yes – *Continue to question 20*
    b. No –*Skip to question 24*
    c. I don't know – *Skip to question 24*

20. Please indicate the sources of PGHD your health system is currently using. *Select all that apply*
    a. Mobile applications (e.g., health app on smartphone)
    b. Wearable devices (e.g., Fitbits, smartwatches)
    c. Registered medical devices (e.g., glucometers, blood pressure monitors)
    d. Patient portal
    e. Other (please specify)

21. Please indicate what clinical specialties are currently collecting PGHD as part of clinical care. *Select all that apply.*
    a. Behavioral Health
    b. Dermatology
    c. Geriatrics/Elder Care
    d. Internal Medicine
    e. Oncology
    f. Orthopedics
    g. Pediatrics
    h. Rehabilitation Services/Medicine
    i. Surgery/Surgical Specialties
    j. Transplant
    k. Other (please specify)

22. Please indicate the types of PGHD your health system is currently collecting. *Select all that apply.*
    a. Health history
    b. Medication history
    c. Symptoms
    d. Biometric data

---

[13] Deering MJ. Issue Brief: Patient-Generated Health Data and Health. Office of the National Coordinator for Health Information Technology. December 2020. https://www.healthit.gov/sites/default/files/pghd_brief_final122013.pdf

e. Treatment history
f. Lifestyle choices
g. Other (please specify)

23. To what extent are PGHD integrated into your health system's EHR?[14] *Please select the option that best reflects current capabilities.*
    a. Full EHR integration (i.e., PGHD data are fully integrated with other data within the EHR and can be plotted along with other data)
    b. Moderate EHR integration (i.e., PGHD data is accessible through EHR via a link to a separate website, with limited customizable views of PGHD data in EHR)
    c. Low EHR integration (i.e., PGHD data accessible through a separate website, and data is available in EHR as images).
    d. Mixed EHR integration (i.e., Some PGHD data are accessible through EHR while others are not)
    e. No EHR integration (i.e., PGHD data not available in EHR)
    f. I don't know

24. {OPTIONAL} Please use the space below to provide any additional information on your health system's collection and use of PGHD. *This question is optional.*

Section 5– Optional Questions

25. {OPTIONAL} What are your health system's future plans for collecting and using PROs in the next 2-4 years? *This question is optional.*

26. {OPTIONAL} What are your health system's future plans for collecting and using PGHD in the next 2-4 years? *This question is optional.*

27. {OPTIONAL} Please include links to any publications or presentations you would like to share regarding your PRO/PGHD work within your health system, Network, and/or PCORnet. *This question is optional.*

---

[14] Ibid.

Appendix B. CRN Summary

The table below summarizes the CRNs participating in PCORnet at the time of the data collection and analysis, July to December 2021.

Clinical Research Network	Network Composition	Partner Organizations
Accelerating Data Value Across a National Community Health Center Network (ADVANCE)	Led by OCHIN, Inc., ADVANCE represents more than 5 million patients at community health centers (CHCs) nationwide. Partners contribute ambulatory patient and community-level data from more than 44.6 million clinic encounters for more than 5 million patients.	OCHIN, Inc. (Lead) Fenway Health Health Choice Network HealthLandscape Oregon Health & Science University Robert Graham Center
Chicago Area Patient-Centered Outcomes Research Network (CAPriCORN)*	CAPriCORN maintains data for 10 million patients from private and public health systems across the Chicago area. Led by Northwestern University, CAPriCORN receives data for patients who received care at partner-affiliated sites in the region, including community-based organizations, outpatient care sites, federally qualified health centers, primary and specialty care practices, and academic medical centers.	Alliance Chicago Cook County Health and Hospitals System Edward Hines Jr. VA Hospital and Jesse Brown Medical Center Loyola University Health System Lurie Children's Hospital of Chicago Northshore University HealthSystem Rush University Medical Center University of Chicago University of Illinois Hospital and Health Sciences System
Greater Plains Collaborative (GPC)	The GPC collected data for more than 20 million patients. Led by the University of Kansas Medical Center Research Institute, the network used its data to focus on three disease cohorts: amyotrophic lateral sclerosis (ALS), breast cancer, and obesity. The network's de-identified database gathered data primarily from electronic health record and billing systems and merged these data with claims from the Centers for Medicare & Medicaid Services to increase data completeness.	University of Kansas Medical Center (Lead) Allina Health, Intermountain Healthcare Marshfield Clinic Research Institute Medical College of Wisconsin University of Iowa Healthcare University of Missouri University of Nebraska Medical Center University of Texas Health Science Center at San Antonio University of Texas Health Science Center at Houston University of Texas Southwestern Medical Center University of Utah Washington University in St. Louis

Clinical Research Network	Network Composition	Partner Organizations
INSIGHT	INSIGHT brought together seven health systems in and around New York City to collect data on 12 million unique patients. Led by Weill Medical College of Cornell University, INSIGHT has six additional partners in the New York area and collects data from electronic health records and Medicare, Medicaid, and commercial insurance claims.	Weill Cornell Medicine (Lead) Albert Einstein College of Medicine Columbia University Irving Medical Center Icahn School of Medicine at Mount Sinai New York-Presbyterian Hospital New York University School of Medicine
OneFlorida	Led by the University of Florida, the network included 11 additional partners populating a database containing information on more than 5 million Florida residents. Data are available since 2012. Data come from patients who consented to release their health information as well as electronic health records from partner organizations, Medicaid and Medicare claims, the Florida Cancer registry, and state vital statistics.	University of Florida – UFHealth (Lead) AdventHealth Bond Community Health Center, Inc. Emory University Florida State University Nicklaus Children's Hospital Orlando Health System Tallahassee Memorial Healthcare Tampa General Hospital University of Alabama at Birmingham University of Miami and UHealth University of South Florida and USFHealth
Path Towards a Learning Health System (PaTH)	Led by the University of Pittsburgh, PaTH comprises seven health systems in the Mid-Atlantic and midwestern regions. The network had data on more than 13 million patients as of July 30, 2019. Data sources included Medicare and Medicaid claims, EHRs, relevant laboratory results, and patient-reported surveys	University of Pittsburgh (Lead) Geisinger Health System Johns Hopkins Institute for Clinical & Translational Research Johns Hopkins Medicine Penn State College of Medicine Penn State Health Medical Center Temple University School of Medicine The Ohio State University The Ohio State University Medical Center University of Michigan Institute for Clinical & Health Research UPMC

Clinical Research Network	Network Composition	Partner Organizations
PEDSnet	PEDSnet is a national pediatric learning health system. Led by Children's Hospital of Philadelphia, PEDSnet was made up of eight pediatric medical centers, whose primary markets were located in 12 states, with data on more than six million children, adolescents, and young adults. PEDSnet's data encompasses all pediatric diseases and specialties. The main data sources are electronic health records. Additional data were collected by individual studies from health insurance and medication claims, birth records, and child and parent surveys.	Children's Hospital of Philadelphia (Lead) Ann & Robert H. Lurie Children's Hospital of Chicago Boston Children's Hospital Children's Hospital Colorado Cincinnati Children's Hospital Medical Center Nationwide Children's Hospital Nemours Children's Health System St. Louis Children's Hospital Seattle Children's Research Institute Stanford Children's Health
Research Action for Health (REACHnet)	Led by the Louisiana Public Health Institute (LPHI), REACHnet is a CRN that represented almost 6.4 million patients at four healthcare systems in Louisiana and Texas.	Louisiana Public Health Institute (Lead) Baylor Scott & White Health Research Institute Ochsner Health System Tulane Medical Center University Medical Center New Orleans
Stakeholder, Technology and Research (STAR)	Led by Vanderbilt University Medical Center, the STAR Network had collected electronic health record data for more than 20 million patients as of August 2018. The network collected data from academic health centers; community hospitals; and a variety of outpatient practices including primary care, specialty practices, and safety net facilities serving diverse populations.	Vanderbilt University Medical Center (Lead) Duke University Health Sciences South Carolina Mayo Clinic Meharry Medical College The University of North Carolina at Chapel Hill Vanderbilt Health Affiliated Network Wake Forest Baptist Health

*CAPriCORN is no longer participating in PCORnet

Appendix C. Expanded Methods

C.1 Analytic Approach and Research Questions

We developed guiding research questions focused on three domains to inform the development of a survey and key informant interview guides to guide our analysis. Table C-1 below identifies those domains and summarizes our research questions.

Table C-1. Domains and Key-Questions

Domains	Research Questions
Current Landscape of PRO Data and PGHD Collection and Use across PCORnet® CRNs	1. What is the current state of PRO and PGHD collection (in routine clinical care or research purposes) in health systems within PCORnet® CRNs? 2. What PRO measures are currently collected and are there commonly used measures across health systems? 3. What are the primary sources of PGHD (e.g., Bluetooth enabled devices, wearable technology)? 4. To what extent are PROs and PGHD integrated into the EHRs?
Barriers to PRO and PGHD Use for Research Purposes	5. What are the challenges to harmonizing PROs and PGHD from other sources (e.g., REDCap) into the PCORnet® CDM? 6. What are the challenges to accessing or using PRO data within PCORnet® CRNs? 7. What data quality issues (e.g., data completeness, availability of structured data) exist for PRO data currently available through DataMarts?
Opportunities to Enhance PCORnet Data Infrastructure to Expand PRO Data and PGHD Availability	8. What are the future opportunities to enhance the PCORnet data infrastructure to support the use of PROs for research? 9. What are the longer-term opportunities for the capture and use of PGHD for research within the PCORnet community? 10. What parallel efforts focused on PROs and/or PGHD can inform the enhancement of PCORnet data infrastructure?

C.2 Survey of Health Systems Participating in PCORnet

In order to better understand the current PRO and PGHD landscape across PCORnet® CRNs, we fielded an online survey using the Qualtrics platform for four weeks from August 2021 to September 2021. The survey was emailed by the Coordinating Center for PCORnet to each CRN with instructions to distribute the survey to their participating health systems (see Appendix A). Of the 75 health systems participating in PCORnet, 53 systems completed the survey. One health system may include many sites, therefore the prime site for each health system participating in PCORnet completed the survey. The intent of the survey was to better understand 1) how PROs and PGHD were being used in clinical and research settings, and 2) to what extent PROs and PGHD were integrated into EHRs and the PCORnet® CDM.

C.3 Literature Review

We conducted a targeted search of peer-reviewed and grey literature with a focus on literature from the past five years (i.e., no earlier than 2016); however, we included some earlier background literature relevant to PCORnet® CRNs and their history of PRO data capture. For published literature, we searched PubMed, and for grey literature we searched Google, professional organization websites (e.g., AMIA), research and policy organizations, and government websites (e.g., Office of the National Coordinator for Health Information, Assistant Secretary for Planning and Evaluation). Additionally, we reviewed resources provided by health systems participating in PCORnet in their responses to the NORC survey.

C.4 Key Informant Interviews

We conducted interviews with nine key informants to understand the current state of PROs and PGHD across PCORnet® CRNs, as well as challenges and opportunities. Key informants included perspectives both internal and external to PCORnet; a staff member from the Coordinating Center for PCORnet; two members of PCORI's Board of Governors; representatives from PCORnet® CRNs that have extensive informatics and PRO backgrounds (PaTH, STAR, and PEDSnet); and data infrastructure experts who have worked extensively with PROs.

C.5 Webinar

On December 14, 2021, NORC convened a 90-minute webinar to discuss the challenges and opportunities outlined in the White Paper Executive Summary. In total, 66 individuals attended the webinar, including representatives from PCORnet Network Partners, the Coordinating Center for PCORnet, government entities, NORC, and PCORI, as well as attendees from industry and institutions not participating in PCORnet.

The webinar consisted of presentations by NORC and PCORI providing background on PCORnet and the initial survey effort, followed by three expert-led sections from key informants on each of three major themes: opportunities for leveraging PRO data collected during clinical care, opportunities for leveraging PRO data collected during research, and opportunities to capture PGHD. Audience input was solicited on each theme in the form of questions posed directly to them via the speakers, polls that asked them to prioritize opportunities within each theme, Q&A between speakers and audience, and a live chat conversation. NORC produced a webinar summary and incorporated input from the speakers and audience into this White Paper.

Figure C-1. Search Terms for Grey and Published Literature and Illustrative Resources

Area	Search Terms
Data Infrastructure	Medical Informatics[Mesh], "Electronic Health Records[Mesh], Research Data Warehouse
PCORnet	"PCORnet", "Clinical Research Network"
PROs/PGHD	Patient Reported Outcome Measure[Mesh], "patient-reported outcomes", patient generated health data", Patient Generated Health Data[MeSH], "person-generated health data", "consumer-generated health data", "digital health data"
Illustrative Resources	
Collecting, Integrating, and Disseminating Patient-Reported Outcomes for Research in a Learning Healthcare System[34] • Health Data Processes: A Framework for Analyzing and Discussing Efficient Use and Reuse of Health Data With a Focus on Patient-Reported Outcome Measures[35] • Factors Associated With Increased Collection of Patient-Reported Outcomes Within a Large Health Care System[36] • ONC Patient-Reported Outcomes through Health IT Project[37] • Bachmann PCORnet® Steering Committee PROM Presentation• Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records[38]• The PCORnet Patient-Reported Outcomes (PRO) Common Measures Working Group (CMWG): Final Report	

Figure C-2. Key Informants by Stakeholder Type

Stakeholder Type	Key Informant Name and Organization
Coordinating Center for PCORnet and PCORnet® CRNs	• Keith Marsolo, Coordinating Center for PCORnet • Justin Bachmann, STAR • Harold Lehmann, PaTH • Charles Bailey, PEDSnet
PCORI Board of Governors	• Russell Howerton, Wake Forest Baptist Medical Center • Ellen Sigal, Friends of Cancer Research
PRO/PGHD data infrastructure	• Kenneth Mandl, Harvard Medical School • Raheel Sayeed, Harvard Medical School • Daniella Meeker, University of Southern California

Appendix D. Supporting Figures

Multiple PCORnet® CRNs have collected PRO measures as part of research efforts. For example, STAR and PATH have conducted multiple studies utilizing PROs; GPC and OneFlorida have also conducted some PRO-related research. The most notable instance of cross-PCORnet® CRN collaboration on PRO collection and use is the ADAPTABLE study, which seven CRNs have participated in.[39] Figure D-1 provides illustrative examples of PRO data collection in research.

Figure D-1. Illustrative Examples of PCORnet® CRNs using PRO Data for PCOR/CER

PCORnet® CRN	Illustrative Examples of PRO/PGHD use for PCOR/CER
Multiple	The ADAPTABLE study is the first interventional trial conducted within the PCORnet electronic data infrastructure.[40] As part of the trial, all study visits were completed in a web portal; during these visits, which occurred every 3-6 months, researchers collected PROs from participants, along with additional data.[41] Patient information is supplemented through queries of the PCORnet® CDM, EHRs, and claims data, i.e., confirming patient-reported hospitalizations via queries.[42]
PaTH	PATH researchers studied the implementation of PROMs in routine clinical care for patients with heart failure and conducting cross-institutional analyses of PROM data. The team successfully integrated three PROMs into the EHRs of three academic health centers: the KCCQ-12; PROMIS Global Health scale; and the Patient Health Questionnaire (PHQ-2).[43] Following the data's integration, it was successfully queried using the PCORnet® CDM.[44] Based on the query, researchers were able to make some demographic and clinical comparisons between patients that did and did not complete PROs.[45]
STAR	Researchers used PROs to evaluate the effect of perceived health competence, a patient's belief in their ability to achieve health-related goals, on cumulative physical activity levels in the Mid-South Coronary Heart Disease Cohort Study (MCHDCS).[46] Perceived health competence was assessed with a short form of the Perceived Health Competence Scale. Various components of the patients' health and background was measured using items from the following scales: PROMIS, NATS, ENRICHD, Health Literacy Screen, and the 3-item Subjective Numeracy Scale.[47] Among other findings, researchers concluded that perceived health competence was highly associated with physical activity after multivariable adjustment.[48]

Related or parallel efforts focused on PRO and/or PGHD collection may address broader challenges and help advance the field, creating downstream benefits for PCORnet. Figure D-2 provides a brief description of other efforts, including the scope of each initiative and implications for PCORnet® CRNs.

Figure D-2. Relevant Initiatives Focused on PRO/PGHD Data Collection and Implications for PCORnet

Organization or Entity	Description	Implications for PCORnet® CRNs
Advancing PRO/PGHD Data Infrastructure		
Assistant Secretary for Planning and Evaluation (ASPE)	Through the Patient-Centered Outcomes Research (PCOR) Trust Fund, ASPE funds a portfolio of data infrastructure projects.[49] The funded project *Advancing the Collection and Use of Patient-Reported Outcomes (PROs) through Health Information Technology (IT)* created the Patient Reported Outcomes FHIR Implementation Guide.[50] In addition, ASPE recently identified opportunities to support research data networks engaged in PCOR, including PCORnet.[51]	Tools and resources produced through ASPE-funded data infrastructure projects may support health systems in advancing the collection of PROs and PGHD. Future funded work may generate data infrastructure solutions applicable to research data networks.
Office of the National Coordinator for Health Information Technology (ONC)	ONC has supported a number of efforts to advance the collection and use of PROs and other PGHD.[52] In particular, projects funded by ASPE under the PCOR Trust Fund have focused on improved data infrastructure for PROs/PGHD.[53]	Tools and resources produced through ONC data infrastructure projects may support health systems in advancing the collection of PROs and PGHD. Future funded work may generate data infrastructure solutions applicable to research data networks.
Centers for Medicare and Medicaid Services (CMS)	Broadly, CMS has advanced the collection of PROs through quality measure initiatives. The CMS Meaningful Measures 2.0 program aims to ease the burden of quality measurement as well as modernize quality measurement through the advancement of digital quality measures. The program aims to make a number of advancements related to the collection of PROs including simplifying PRO measures and addressing integration within the EHR, developing PRO measures embedded into workflows, and advancing the use of PROMIS.[54]	CMS programs may incentivize health systems to collect electronic PROs and integrate PROs within the EHR.
PCORI	PCORI's methods portfolio includes a current recurring funding announcement on improving methods for PCOR that can include projects that address methodological issues related to data research networks, such as PROs.	The methods portfolio includes projects that leverage PCORnet infrastructure and seek to expand the methodological capabilities for the Network.

Organization or Entity	Description	Implications for PCORnet® CRNs
PRO/PGHD Conveners		
NIH Health Care Systems Research Collaboratory (NIH Collaboratory)	The NIH Collaboratory is creating an infrastructure for collaborative research within healthcare to improve the conduct of clinical trials. One of the five topic-based Core Working Groups focuses on patient-centered outcomes. The Patient-Centered Outcomes Core works with the Collaboratory to create guidelines and best practices on a variety of subjects including PRO measure selection and development; PRO data collection system compatibility with EHRs; and analysis of PRO endpoints. The Core has held several workshops and published white papers on these topics.[55]	The NIH Collaboratory may serve in the role of a convenor to address broader challenges around the standardized collection and integration of PRO measures. There may be downstream impacts on the availability for PRO data for PCORnet® CRNs if guidelines from the NIH Collaboratory are more widely adopted.
Patient-Reported Outcomes Tools: Engaging Users & Stakeholders (PROTEUS) Consortium	Lead by domestic and international experts in PROs, the PROTEUS Consortium partners with patient, clinician, research, and regulatory groups from the U.S. and other countries to promote systematic use of PROs in clinical trials.[56]	The PROTEUS Consortium may help advance discussions about the selection of meaningful PRO measurement and the selection of PROs in research.
National Quality Forum (NQF)	NQF works towards researching and endorsing quality measures using a consensus-based stakeholder committee process.[57] Notably, NQF convened stakeholders for a 2012 project on *PROs in Performance Measures*. The final report detailed methods for evaluating and transforming PROs into Patient-Reported Outcomes Performance Measures.[58]	NQF may serve as convening organization to advance the collection of a standard set of PRO measures across health systems.

References

---

[1] Locklear TD, et al. Reaching Consensus on Patient-Centered Definitions: A Report from the Patient-Reported Outcomes PCORnet Task Force. April 2015. Retrieved October 27, 2021 from https://dcricollab.dcri.duke.edu/sites/NIHKR/KR/Reaching%20Consensus_April_9_2015.pdf

[2] Deering MJ. Issue Brief: Patient-Generated Health Data and Health. Office of the National Coordinator for Health Information Technology. December 2020. Retrieved October 27, 2021 from https://www.healthit.gov/sites/default/files/pghd_brief_final122013.pdf

[3] Acaster S, Cimms T, and Lloyd A. The Design and Selection of Patient-Reported Outcomes Measures (PROMs) for Use in Patient Centered Outcomes Research. 2012. Available at: https://www.pcori.org/assets/The-Design-and-Selection-of-Patient-Reported-Outcomes-Measures-for-Use-in-Patient-Centered-Outcomes-Research.pdf

[4] Snyder C, and Wu, A.W., eds. Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Baltimore, MD: Johns Hopkins University. 2017. Funded by Patient-Centered Outcomes Research Institute (PCORI); JHU Contract No. 10.01.14 TO2 08.01.15. Available at: http://www.pcori.org/document/users-guide-integrating-patient-reported-outcomes-electronic-health-records

[5] PCORI. (2020). PCORI Funding Reauthorization. https://www.pcori.org/sites/default/files/PCORI-Funding-Reauthorization-In-Brief.pdf

[6] Locklear T, Staman K, Hudson K, Mularski R, Hills M, Cope E, Wahba S, Zirkle M, Kripalani S. Reaching Consensus on Patient Centered Definitions: a Report from the Patient-Reported Outcomes PCORnet Task Force. April 2015. Retrieved October 27, 2021, from https://dcricollab.dcri.duke.edu/sites/NIHKR/KR/Reaching%20Consensus_April_9_2015.pdf

[7] Timbie J, Rudin R, Towe V, Chen E, Hunter L, Case S, Kotzias V, Predmore Z, Moen S, and Ridgely S. National Patient-Centered Clinical Research Network (PCORnet) Phase I: Final Evaluation Report. Santa Monica, CA: RAND Corporation, 2015. https://www.rand.org/pubs/research_reports/RR1191.html.

[8] Timbie J, Rudin R, Towe V, Chen E, Hunter L, Case S, Kotzias V, Predmore Z, Moen S, and Ridgely S. National Patient-Centered Clinical Research Network (PCORnet) Phase I: Final Evaluation Report. Santa Monica, CA: RAND Corporation, 2015. https://www.rand.org/pubs/research_reports/RR1191.html.

[9] Timbie J, Rudin R, Towe V, Chen E, Hunter L, Case S, Kotzias V, Predmore Z, Moen S, and Ridgely S. National Patient-Centered Clinical Research Network (PCORnet) Phase I: Final Evaluation Report. Santa Monica, CA: RAND Corporation, 2015. https://www.rand.org/pubs/research_reports/RR1191.html.

[10] PCORnet. Common Data Model (CDM) Specification, Version 3.0. July 2015. Retrieved October 27, 2021 from https://www.medschool.lsuhsc.edu/ortho/docs/2015-07-29-PCORnet-Common-Data-Model-v3dot0-RELEASE.pdf

[11] PCORI. Common Data Model (CDM) Specification, Version 6.0. October 2020. Retrieved October 27, 2021 from https://pcornet.org/wp-content/uploads/2020/12/PCORnet-Common-Data-Model-v60-2020_10_221.pdf

---

[12] PCORI. (2021, February 08). Prioritizing Principles for Infrastructure Funding Relating to PCORnet. Retrieved April 19, 2021, from https://www.pcori.org/document/prioritizing-principles-infrastructure-funding-relating-pcornet

[13] PCORnet. Engagement. Retrieved October 27, 2021 from https://pcornet.org/engagement/

[14] Forrest CB, McTigue KM, Hernandez AF, et al. PCORnet 2020: current state, accomplishments, and future directions. J Clin Epidemiol. 2021;129:60-67. doi:10.1016/j.jclinepi.2020.09.036

[15] Bachmann JM, Posch DR, Hickson GB, Pinson CW, Kripalani S, Dittus RS, Stead WW. Developing an Implementation Strategy for Systematic Measurement of Patient-Reported Outcomes at an Academic Health Center. J Healthc Manag. 2020 Jan-Feb;65(1):15-28.

[16] HealthMeasures. Epic. Retrieved November 12, 2021, from https://www.healthmeasures.net/implement-healthmeasures/administration-platforms/epic

[17] LOINC. Patient Reported Outcomes Measurement Information System (PROMIS). Retrieved November 12, 2021, from https://loinc.org/panels/category/survey-instruments/patient-reported-outcomes-measurement-information-system-promis/

[18] Electronic Health Record Access to Seamless Integration of Patient-Reported Outcomes (EASIPRO). Retrieved November 12, 2021, from https://sites.northwestern.edu/easipro/

[19] PCORnet. Data. Retrieved October 27, 2021 from https://pcornet.org/data/

[20] Qualls LG, Phillips TA, Hammill BG, Topping J, Louzao DM, Brown JS, Curtis LH, Marsolo K. Evaluating Foundational Data Quality in the National Patient-Centered Clinical Research Network (PCORnet). EGEMS (Wash DC). 2018 Apr 13;6(1):3.

[21] PCORnet. PCORnet: Progress Dashboard At a Glance. July 2021. Retrieved November 12, 2021, from https://pcornet.org/wp-content/uploads/2021/10/PCORnet-Progress-Dashboard-At-a-Glance.pdf

[22] PCORnet Distributed Research Network Query Tool. Retrieved from November 12, 2021, https://querytool.pcornet.org/login?returnUrl=https%3A%2F%2Fquerytool.pcornet.org%2F

[23] Carton T, Marsolo K, Block J. PCORnet COVID-19 Common Data Model Design and Results. June 5, 2021. Retrieved October 27, 2021 from https://dcricollab.dcri.duke.edu/sites/NIHKR/KR/GR-Slides-06-05-20.pdf

[24] REDCap. Library. Retrieved October 27, 2021 from https://projectredcap.org/resources/library/

[25] REDCap. REDCap Shared Library. Retrieved October 27, 2021 from https://redcap.vanderbilt.edu/consortium/library/search.php

[26] Waitman R. PCORnet Observations: After 13 years, has "Meaningful Use" Generated Data that is Meaningful for Research? Presented to the ONC Interoperability Standards Priorities Task Force (ISPTF); April 16, 2021. Retrieved October 27, 2021 from https://www.healthit.gov/sites/default/files/facas/2021-04-16_Presentation_on_PCORNET.pdf

[27] PaTH Network. REDCap python code. September 2018. Retrieved October 27, 2021 from https://github.com/dbmi-pitt/path-redcap-to-cdm

[28] Lister Hill National Center for Biomedical for Biomedical Communications. LHC FHIR Tools. June 2021. Retrieved December 21, 2021, from https://lhcforms.nlm.nih.gov/.

---

[29] Tiase VL, Hull W, McFarland MM, Sward KA, Del Fiol G, Staes C, Weir C, Cummins MR. Patient-generated health data and electronic health record integration: protocol for a scoping review. BMJ Open. 2019 Dec 17;9(12):e033073.

[30] Cortez A, Hsii P, Mitchell E, Riehl V, Smith P. Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024. January 2018. Retrieved November 12, 2021, from https://www.healthit.gov/sites/default/files/onc_pghd_final_white_paper.pdf

[31] Lavallee DC, Lee JR, Austin E, Bloch R, Lawrence SO, McCall D, Munson SA, Nery-Hurwit MB, Amtmann D. mHealth and patient generated health data: stakeholder perspectives on opportunities and barriers for transforming healthcare. Mhealth. 2020 Jan 5;6:8.

[32] Pletcher MJ, Fontil V, Carton T, Shaw KM, Smith M, Choi S, Todd J, Chamberlain AM, O'Brien EC, Faulkner M, Maeztu C, Wozniak G, Rakotz M, Shay CM, Cooper-DeHoff RM. (2020) The PCORnet Blood Pressure Control Laboratory: A Platform for Surveillance and Efficient Trials. *Circ Cardiovasc Qual Outcomes,* 13(3):e006115. doi: 10.1161/CIRCOUTCOMES.119.006115.

[33] Eureka. CCS Investigators Awarded PCORI Contract to Study Participant-Reported Impact of COVID-19 Policies. (2020). Retrieved February 20, 2022, from: https://info.eurekaplatform.org/ccs-investigators-awarded-pcori-contract-to-study-participant-reported-impact-of-covid-19-policies/

[34] Harle, C. A., Lipori, G., &; Hurley, R. W. (2016). Collecting, Integrating, and Disseminating Patient-Reported Outcomes for Research in a Learning Healthcare System. *EGEMs (Generating Evidence & Methods to Improve Patient Outcomes)*, 4(1), 13. doi:10.13063/2327-9214.1240

[35] Hjollund, N. H., Valderas, J. M., Kyte, D., & Calvert, M. J. (2019). Health data Processes: A framework for analyzing and Discussing efficient use and reuse of health data with a focus on patient-reported outcome measures. *Journal of Medical Internet Research*, 21(5). doi:10.2196/12412

[36] Sisodia, R. C., Dankers, C., Orav, J., Joseph, B., Meyers, P., Wright, P.Sequist, T. D. (2020). Factors associated with increased collection of patient-reported outcomes within a large health care system. *JAMA Network Open*, 3(4). doi:10.1001/jamanetworkopen.2020.2764

[37] Patient-Reported Outcomes through Health IT Project. (2020, March 27). Retrieved April 19, 2021, from https://www.healthit.gov/topic/scientific-initiatives/pcor/patient-reported-outcomes-through-healthit-pro

[38] Snyder C, and Wu, A.W., eds. Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Baltimore, MD: Johns Hopkins University. 2017. Funded by Patient-Centered Outcomes Research Institute (PCORI); JHU Contract No. 10.01.14 TO2 08.01.15. Available at: https://www.pcori.org/document/users-guide-integrating-patient-reported-outcomes-electronic-health-records

[39] PCORnet. (2021). Inaugural PCORnet-Powered Study Delivers Insights And Inspiration For Novel Trial Design. Retrieved February 21, 2022, from: https://pcornet.org/news/inaugural-pcornet-powered-study-delivers-insights-and-inspiration-for-novel-trial-design/

---

[40] PCORnet. (2021). Inaugural PCORnet-Powered Study Delivers Insights And Inspiration For Novel Trial Design. Retrieved February 21, 2022, from: https://pcornet.org/news/inaugural-pcornet-powered-study-delivers-insights-and-inspiration-for-novel-trial-design/

[41] Jones WS, Mulder H, Wruck LM, Pencina MJ, et al. Comparative Effectiveness of Aspirin Dosing in Cardiovascular Disease. N Engl J Med. 2021 May 27;384(21):1981-1990. doi: 10.1056/NEJMoa2102137. Epub 2021 May 15.

[42] Jones WS, Mulder H, Wruck LM, Pencina MJ, et al. Comparative Effectiveness of Aspirin Dosing in Cardiovascular Disease. N Engl J Med. 2021 May 27;384(21):1981-1990. doi: 10.1056/NEJMoa2102137. Epub 2021 May 15.

[43] PaTH Network. Implementation of Patient-Reported Outcomes Measurement in Routine Clinical Practice for Heart Failure Patients in PCORnet. Retrieved February 21, 2022, from: https://www.pathnetwork.org/Research/Implementation_Patient_Reported_Outcomes_Measurement_Routine_Clinical_Practice_Heart_Failure_Patients_PCORnet.html

[44] PaTH Network. Implementation of Patient-Reported Outcomes Measurement in Routine Clinical Practice for Heart Failure Patients in PCORnet. Retrieved February 21, 2022, from: https://www.pathnetwork.org/Research/Implementation_Patient_Reported_Outcomes_Measurement_Routine_Clinical_Practice_Heart_Failure_Patients_PCORnet.html

[45] PaTH Network. Implementation of Patient-Reported Outcomes Measurement in Routine Clinical Practice for Heart Failure Patients in PCORnet. Retrieved February 21, 2022, from: https://www.pathnetwork.org/Research/Implementation_Patient_Reported_Outcomes_Measurement_Routine_Clinical_Practice_Heart_Failure_Patients_PCORnet.html

[46] Bachmann, J. M., Mayberry, L. S., Wallston, K. A., Huang, S., Roumie, C. L., Muñoz, D., Patel, N. J., & Kripalani, S. (2018). Relation of Perceived Health Competence to Physical Activity in Patients With Coronary Heart Disease. The American journal of cardiology, 121(9), 1032–1038. https://doi.org/10.1016/j.amjcard.2018.01.024

[47] Bachmann, J. M., Mayberry, L. S., Wallston, K. A., Huang, S., Roumie, C. L., Muñoz, D., Patel, N. J., & Kripalani, S. (2018). Relation of Perceived Health Competence to Physical Activity in Patients With Coronary Heart Disease. The American journal of cardiology, 121(9), 1032–1038. https://doi.org/10.1016/j.amjcard.2018.01.024

[48] Bachmann, J. M., Mayberry, L. S., Wallston, K. A., Huang, S., Roumie, C. L., Muñoz, D., Patel, N. J., & Kripalani, S. (2018). Relation of Perceived Health Competence to Physical Activity in Patients With Coronary Heart Disease. The American journal of cardiology, 121(9), 1032–1038. https://doi.org/10.1016/j.amjcard.2018.01.024

[49] Office of the Assistant Secretary for Planning and Evaluation. Explore the OS-PCORTF Project Profiles. Retrieved October 27, 2021 from https://aspe.hhs.gov/collaborations-committees-advisory-groups/os-pcortf/explore-portfolio

[50] HL7® FHIR® Implementation Guide. Patient Reported Outcomes FHIR Implementation Guide, Release 0.2.0. March 2019. Retrieved October 27, 2021 from http://hl7.org/fhir/us/patient-reported-outcomes/2019May/

[51] Lang L, Smith S, Trevio M, et al. Research Data Networks and Patient-Centered Outcomes Research Trends and Opportunities: Scan and Interviews with Key Informants. July 2021. Retrieved October 27, 2021 from https://aspe.hhs.gov/sites/default/files/2021-07/PCOR%20Research%20Network%20Landscape%20Report_Final_07_14_2021_508.pdf

---

[52] Office of the National Coordinator for Health Information. Patient-Generated Health Data. Retrieved October 27, 2021 from https://www.healthit.gov/topic/scientific-initiatives/patient-generated-health-data

[53] Office of the National Coordinator for Health Information. Building Data Infrastructure to Support Patient-Centered Outcomes Research (PCOR). Retrieved October 27, 2021 from https://www.healthit.gov/topic/scientific-initiatives/building-data-infrastructure-support-patient-centered-outcomes-research

[54] Centers for Medicare and Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. March 2021. Retrieved October 27, 2021 from https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization

[55] NIH Collaboratory Living Textbook. Patient-centered Outcomes. Retrieved October 27, 2021 from https://rethinkingclinicaltrials.org/cores-and-working-groups/patient-reported-outcomes-2/

[56] Patient-Reported Outcomes Tools: Engaging Users & Stakeholders (PROTEUS) Consortium. About PROTEUS. Retrieved October 27, 2021 from https://more.bham.ac.uk/proteus/about-proteus/

[57] National Quality Forum. NQF’s Work in Quality Measurement. Retrieved October 27, 2021 from https://www.qualityforum.org/about_nqf/work_in_quality_measurement/

[58] National Quality Forum. Patient-Reported Outcomes. Retrieved October 27, 2021 https://www.qualityforum.org/Patient-Reported_Outcomes.aspx.